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Key Inforbits

- Herceptin[®] for breast cancer
- MedWatch for acetaminophen, Tamiflu[®], ESAs
- Pharmacist benefits in counseling JAMA
- Diagnosis by GoogleTM
- Duct tape not so good?
- HAPPY THANKSGIVING

NEW DRUGS, and other related stuff ...

New Indication ... The FDA has expanded the approved use of **Herceptin**[®] (**trastuzumab** by Genentech), to include, in combination with other cancer drugs, treatment of HER2 positive breast cancer after surgery (lumpectomy or mastectomy). The two studies leading to this new approved indication were conducted by the National Cancer Institute-sponsored Cooperative Groups, a multicenter clinical trials group. Patients in both trials received standard chemotherapy after surgery for breast cancer; approximately half the patients were also given Herceptin[®]. The results from both trials, which included information on nearly 4,000 women, were combined and analyzed in 2005. Due to positive results, the National Cancer Institute ended the studies early. The most serious side effect of Herceptin[®] is heart failure (weakening of the heart muscle) that requires medical treatment. Due to the risk of heart disease, only certain patients should receive the drug, including:

- Only patients whose tumors are HER2 Positive
- Patients who do not have heart failure or weak heart muscle (cardiomyopathy).

Patients must be screened for heart function before beginning and during Herceptin treatment. FDA expands use of Herceptin for early stage breast cancer after primary therapy. *FDA News*. 2006 Nov 16; P06-188.

http://www.fda.gov/bbs/topics/NEWS/2006/NEW01511.html

MedWatch ... The FDA and Perrigo Company notified the public of a **voluntary recall of 383 lots of acetaminophen 500 mg caplets** manufactured and distributed under various storebrands as a result of small metal fragments found in a limited number of these caplets. Consumers can determine if they are in possession of a recalled product by locating the batch number printed on the container label. A list of stores that carry store-brands potentially affected by this recall, as well as batch numbers affected, is located on FDA's website (referenced below). To date, there have been no reports of illnesses or injuries received related to this problem and no consumer complaints have been reported to the FDA or to Perrigo. The FDA believes the probability of serious adverse health consequences is remote; however, if a consumer were to swallow an affected caplet, it could result in minor stomach discomfort and/or possible cuts to the mouth or throat. Consumers should consult their physician if they suspect they've been harmed by use of this product.

Read the complete MedWatch 2006 Safety Summary, including links to the FDA News Release, Perrigo Voluntary Product Recall Customer List, and Perrigo Recalled Batches, at: http://www.fda.gov/medwatch/safety/2006/safety06.htm#acetaminophen

MedWatch ... Roche and FDA notified healthcare professionals of revisions to the PRECAUTIONS/Neuropsychiatric Events and Patient Information sections of the **prescribing information for Tamiflu**[®], indicated for the treatment of uncomplicated acute illness due to influenza infection in patients 1 year and older who have been symptomatic for no more than 2 days and for the prophylaxis of influenza in patients 1 year and older. There have been postmarketing reports, mostly from Japan, of self-injury and delirium with the use of Tamiflu[®] in patients with influenza. People with the flu, particularly children, may be at an increased risk of self-injury and confusion shortly after taking Tamiflu[®] and should be closely monitored for signs of unusual behavior. A healthcare professional should be contacted immediately if the patient taking Tamiflu[®] shows any signs of unusual behavior.

Read the complete MedWatch 2006 Safety Summary, including links to the Dear Healthcare Professional letter, prescribing information and patient package insert, at: http://www.fda.gov/medwatch/safety/2006/safety06.htm#tamiflu

MedWatch ... FDA notified healthcare professionals of a new study showing that patients treated with an erythropoiesis-stimulating agent (ESA) and dosed to a target hemoglobin concentration of 13.5 g/dL are at a significantly increased risk for serious and life threatening cardiovascular complications, as compared to use of the ESA to target a hemoglobin concentration of 11.3 g/dL. The "Correction of Hemoglobin and Outcomes in Renal Insufficiency" study* reports the adverse cardiovascular complications as a composite of the occurrence of one of the following events: death, myocardial infarction, hospitalization for congestive heart failure, or stroke. The study findings underscore the importance of following the currently approved prescribing information for Procrit[®], Epogen[®], and Aranesp[®], including the dosing recommendation that the target hemoglobin not exceed 12 g/dL. Read the complete MedWatch 2006 Safety summary, including links to the FDA Public Health Advisory and FDA Information for Healthcare Professionals regarding this issue at: http://www.fda.gov/medwatch/safety/2006/safety06.htm#erythropoiesis *Singh AK, Szczech L, Tang KL, Barnhart H, Sapp S, Wolfson M, Reddan D for the CHOIR Investigators. Correction of anemia with epoetin alfa in chronic kidney disease. *N Engl J Med*. 2006 Nov 16;355(20):2085-98.

FROM THE MEDICAL LITERATURE ...

Preventing Falls Among Older Adults ... Among people 65 years and older, falls are the leading cause of injury deaths and the most common cause of nonfatal injuries and hospital



admissions for trauma. Each year in the United States, nearly one third of older adults experience a fall. In 2003, more than 13,700 people 65 years or older died of fall-related injuries. Another 1.8 million were treated in emergency departments for nonfatal injuries related to falls. The total direct cost for falls among older adults in 2000 was about \$19 billion. Given the growing population of this age group, this cost is expected to reach \$43.8 billion by 2020. To learn more about falls among

older adults and what can be done to prevent them, check out the materials that are included in the following "Tool Kit" from the CDC.

http://www.cdc.gov/ncipc/duip/preventadultfalls.htm

More evidence of pharmacist benefit ... A recent study at a Veterans Administration facility studied patient compliance in 200 patients aged 65 years or greater. With a combination of pharmacist counseling involvement and a blister-pack dispensing operation, patient compliance with chronic medications (for hypertension and hypercholesterolemia) increased about 30% to

over 95%, with attendant favorable effects on blood pressure and plasma lipids. An accompanying editorial points out some strengths and weaknesses of the approach and suggestions for "next time." A good study to read. Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol. *JAMA*. 2006 Nov 13;296 (doi:10.1001/jama.296.21.joc60162). Simpson RJ Jr, Challenges for improving medication adherence. *JAMA*. 2006 Nov 13;296

(doi:10.1001/jama.296.21.jed60074).

Diagnosis by GoogleTM ... After a patient provided a correct diagnosis for an unusual case by finding it on GoogleTM, two physicians conducted a test. Using 26 established cases, they used key words to attempt to find a correct diagnosis using GoogleTM; it provided such in 58% of cases. The authors make the point that their search was likely more efficient and thus correct more of the time due to their background expertise, but also, since patients are "doing it themselves" practitioners need to be proficient with this added diagnostic tool. Tang H, Ng JHK. Googling for a diagnosis – use of Google as a diagnostic aid: Internet based study. *BMJ* 2006 Nov 10 (online): doi:10.1136/bmj.39003.640567.AE . www.bmj.com

Reviews of Note ...

- Wenzel RP, Fowler AA III. Acute bronchitis. *N Engl J Med.* 2006 Nov 16;355(20):2125-2130.
- Hachem SB, Mooradian AD. Familial dyslipidaemias: An overview of genetics, pathophysiology and management. *Drugs*. 2006;66(15):1949-69.
- Henness S, Keam SJ. Vildagliptin. Drugs. 2006;66(15):1989-2001.
- Hoy SM, Wagstaff AJ. Panitumumab: In the treatment of metastatic colorectal cancer. *Drugs*. 2006;66(15):2005-14.
- Mahid SS, Minor KS, Soto RE, Hornung CA, Galandiuk S. Smoking and inflammatory bowel disease: A meta-analysis. *Mayo Clin Proc.* 2006 Nov;81(11):1462-71.

FROM THE LAY LITERATURE about medicine ...

Duct Tape Dives ... in a story based on an article in Archives of Pediatrics and Adolescent

Medicine, investigators showed in placebo in the treatment of warts. However, six patients achieved (clinically significant??). A reported on patients self-reporting. Sounds



103 children duct tape fared no better than This counters a 2002 study in the same journal. results with duct tape with only three on placebo methodological flaw was that results were based like a confirmatory study is in order!

Reuters. Duct tape no magical cure for warts, study finds. *CNN.com* 2006 Nov 6. http://www.cnn.com/2006/HEALTH/11/06/warts.duct.tape.reut/index.html

Jimson weed, rarely abused twice ... In slightly more northern climes, jimson weed (aka, stinkweed, locoweed, moonflower) is in full bloom and readily available. With effects like atropine, a common description of an intoxicated patient is "hot as a hare, blind as a bat, dry as a bone, red as a beet and mad as a hatter." Generally, the plant pods contain seeds that are brewed or eaten. Effects are sometimes delayed, encouraging higher doses. Overdoses can be fatal. If there is any good news, most first time users don't want to repeat the experience. Leinwand D. Jimson weed users chase high all the way to hospital. *USA Today*. 2006 Nov 1. http://www.usatoday.com/news/nation/2006-11-01-jimson_x.htm



Update ...

Career in Retail Pharmacy ... The digital edition of *Careers in Retail Pharmacy's Fall 2006* is now available to pharmacy students nationwide. Please use the attached the link to *Career in Retail Pharmacy* to check out the possibilities. This resource is provided by *Drug Store News*. http://www.drugstorenews-digital.com/drugstorenews/200611/

Outcomes Research Fellowships ... Two-year fellowship program, sponsored by Novartis Pharmaceuticals, at three different locations: 1st year at one of three locations, Rutgers University in East Hanover, NJ; Scott & White Health Plan/University of Texas at Temple, TX/Austin, TX; Duke University, Durham, NC. 2nd year is at Novartis Pharmaceuticals in New Jersey. Application is in the DIC, on the bulletin board (along with many others), or contact Kelly Fee, Pharm.D. 862-778-7686, kelly.fee@novartis.com

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Epps TC, Walker PD. Fluoroquinolone consumption and emerging resistance. US *Pharmacist*. 2006 Oct;31(10):47, 48, 53,54.
- DeRuiter J, Holston PL, DeRuiter AP. New drug review. US Pharmacist. 2006 Oct;31(10):117-125.

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

- McEvoy GK, ed. *AHFS Drug Information Essentials 2006-2007*. Bethesda, MD: American Society of Health-System Pharmacists, 2006.
- Meckling KA, ed. *Nutrient-Drug Interactions*. Boca Raton, FL: CRC Taylor & Francis, 2007.
- *Journal of Pharmacy Teaching*. Editor: David P. Zgarrick. Publisher: Pharmaceutical Press Products.



"A new government study has found that the average American car weighs 500 lbs more than it did 10 years ago. However, this is only true if the average American is sitting in the car." -- conan OBrian Icited from *Time* 2006 Oct 30;168(18):22.]



 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