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Key Inforbits

- A couple of new generics on the market
- Several MedWatches to heed
- The "polypill" and secret life of CAM
- Patients & therapists taking pharmacy action
- New residency directory available
- Pandemicflu.gov

NEW DRUGS, and other related stuff ...

New Generics ... Azithromycin is now available generically from at least three manufacturers. They are Pliva Hrvatska, Teva Pharma and Sandoz, Inc. Strengths are 250 mg, 500 mg and 600 mg. For more information, go to Drugs@FDA: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm

Ofloxacin otic solution was approved on November 18, 2005 by the FDA. It is used to treat infections caused by susceptible microorganisms. The reference drug is Floxin[®] Otic Solution.

MedWatch ... New MedWatch Form Available. The FDA released a new MedWatch form for use in voluntarily reporting of adverse events, product-use errors, product defects, and problems related to generic products, on November 1, 2005. Filling out the form takes an average of 36 minutes, according to the government estimate. <u>http://www.fda.gov/medwatch/SAFETY/3500.pdf</u> (form) <u>http://www.fda.gov/medwatch/REPORT/CONSUMER/INSTRUCT.HTM</u> (instructions)

MedWatch ... FDA notified manufacturers of Advair Diskus, Foradil Aerolizer, and Serevent Diskus to update their existing product labels with new warnings and a Medication Guide for patients to alert health care professionals and patients that these medicines may increase the chance of severe asthma episodes and death when those episodes occur. All of these products contain long-acting beta2-adrenergic agonists (LABA). Even though LABAs decrease the frequency of asthma episodes, these medicines may cause asthma episodes to become more severe when they occur. A Medication Guide with information about these risks will be given to patients when a prescription for a LABA is filled or refilled.

Read the complete MedWatch 2005 Safety Summary, including links to the FDA Public Health Advisory and the FDA Drug Information Page that includes links to the Healthcare Professional and Patient Information Sheets, at:

http://www.fda.gov/medwatch/safety/2005/safety05.htm#LABA

MedWatch ...FDA and Novartis Nutrition Corporation notified healthcare professionals of a recall of 2,712 bottles of an enteral feeding formula that was incorrectly labeled as Diabetisource AC 1.5 Liter bottles lot 2135L. The affected product was shipped nationwide and is only distributed to healthcare institutional facilities. The bottles contain sodium and calcium caseinate, components of milk. People with an allergy or severe sensitivity to milk may

run the risk of a serious or life threatening allergic reaction if they consume this product. Healthcare professionals administering Diabetisource AC to patients who have an allergy or sensitivity to milk should immediately stop using this product. Read the complete MedWatch 2005 Safety Summary, including a link to the Novartis Media Release, at: <u>http://www.fda.gov/medwatch/safety/2005/safety05.htm#Diabetisource</u>

FROM THE MEDICAL LITERATURE ...

Drugs and Pregnancy ... A rather disturbing study, the National Ambulatory Medical Care Survey (NAMCS). A sample of 12,681 visits made to 1880 physicians by nonpregnant women aged 14-44 years old was used. The number of prescriptions for a drug in Pregnancy Category D or X were tracked. The outcome was that approximately 7.5% of women received a potential teratogen and among these women <20% received contraceptive counseling. The authors estimate that 450,000 pregnancies may be unintentionally exposed to potential teratogens each year. If you are behind the counter, don't assume your patient knows the risks! Schwarz EB, Maselli J, Norton M, Gonzales R. Prescription of teratogenic medications in United States ambulatory practices. *Am J Med* 2005 Nov;118(11):1240-49.

One pill for all your ills ... Ever heard of the "polypill?" In 2003, two physicians proposed the "polypill" for use as a public health prevention approach to cardiovascular disease. It consists of a statin, beta-blocker, angiotensin converting-enzyme inhibitor, aspirin and folic acid. Their proposal was that adults taking this combination would reduce their chances of an adverse cardiovascular event by 80%. The formulation could be modified based on population characteristics. This article discusses various aspects of this approach. Combination Pharmacotherapy and Public Health Research Working Group. Combination pharmacotherapy for cardiovascular disease. *Ann Intern Med* 2005 Oct 18;143(8):593-99.

The secret lives of CAM ... In an abstract presented at the American Heart Association Scientific Sessions 2005, many more patients are utilizing Complementary Alternative Therapy (CAM) than their physicians know about ... much more. A few facts and figures from the poster presentation include: From a study of 308 heart patients in North America, 56% and 75% of heart specialists and family practitioners, respectively, were aware of their patients use of CAM; only 8% and 13% even asked about it; AND only 39% of patients even thought it important! Abramson B, Chan RH, Kwan K. American Heart Association Scientific Sessions 2005, abstract 2520. http://www.eurekalert.org/pub_releases/2005-11/aha-dap110705.php

Reviews of Note ...

- Plaut M, Valentine MD. Allergic rhinitis. N Engl J Med. 2005 Nov 3;353(18):1934-44.
- Gordon RJ, Lowy FD. Bacterial infections in drug users. *N Engl J Med.* 2005 Nov 3;353(18):1945-54.
- Audi J, Belson M, Patel M, Schier J, Osterloh. Ricin poisoning: A comprehensive review. *JAMA*. 2005 Nov 9;294(18):2342-51.
- Peterson HB, Curtis KM. Long-acting methods of contraception. *N Engl J Med.* 2005 Nov 17;353(20):2169-75.
- Holstege CP, Rusyniak DE. Medical toxicology. *Med Clin N Am.* 2005 Nov;89(6):1067-1442. [15 articles on a wide variety of topics]

- Abramowicz M, ed. Antiviral drugs for prophylaxis and treatment of influenza. *Med Lett Drugs Ther.* 2005 Nov 21;47(1222):93-95.
- Pleasants RA, Haden D. Update on chronic obstructive pulmonary disease. *Consult Pharm.* 2005 Nov;20(11):965-75.
- CDC. Trends in HIV/AIDS diagnoses 33 states, 2001-2004. MMWR 2005 Nov 18;54(45):1149-53. (Review of the latest statistics on prevalence and populations in the U.S. Rates are holding steady with some shifting among subpopulations) <u>http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5445a1.htm</u>

FROM THE LAY LITERATURE about medicine ...

FYI ... 'Exempt' Prescription Products List Issued ... The Drug Enforcement Administration (DEA) on October 31, 2005, issued its newest list of prescription products that are exempt from the Controlled Substances Act yet contain an ingredient in schedule II, III, IV, or V. http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_rx_list_103105.pdf

Bioidentical hormones ... Article that shows another side of the menopause conundrum, that is "natural" or "bioidentical" hormones that are being compounded for women, in lieu of the more traditional but "dangerous" prescription products (eg, Premarin[®], PremPro[®]). Bioidentical hormones are supposed to mimic the hormones produced by the ovary, but commercial products do that as well; and we know that "natural" \neq safe. The primary complaint against the compounded products is the lack of good published trials, so evidence is anecdotal at best. Rubin R. Menopausal women turn to 'natural' hormones. *USA Today* 2005 Nov 6. http://www.usatoday.com/news/health/2005-11-06-bioidentical-hormones_x.htm

Dispensing patients ... A long story in the *New York Times* about an "underground" culture of self-educated patients who commonly diagnosis illness (more commonly mental health issues) for themselves or their friends and then dispense medications (more like a starter kit) from their personal stash. This stash comes from their own prescriptions or perhaps family members, the Internet, or from prescriptions fraudulently obtained from physicians by the patients fabricating or trumping up their own symptoms. Very enlightening article about an apparent subculture. Harmon A. Young, assured and playing pharmacist to friends. *New York Times.com* 2005 Nov 16. http://www.nytimes.com/2005/11/16/health/16patient.html

Now therapists are horning in on our action ... Things are tough enough without therapists trying to push non-drug therapies. According to an article in *USA Today*, data shows that cognitive behavioral therapy is as effective and lasts longer than some of the newer sleep aids being marketed (Ambien[®] and Lunesta[®] were mentioned). Good news for pharmacists though, that trained therapists are few; the bad news is that they are going online with self-guided programs for as little as \$35!

Painter K. Yawning gap in sleep care. USA Today 2005 Nov 20. http://www.usatoday.com/news/health/2005-11-20-sleep-care_x.htm

Star Anise the latest star ... for bird flu. Just in case patients ask about star fruit (or star anise, or bajiao), it contains a starter ingredient (shikimic acid) for oseltamivir (Tamiflu[®]). It is now one of the hottest properties on the planet and 90% is produced in a Chinese province which

is good and bad for the farmers. The fruit has other uses (a licorice flavor) and the fruit itself is not of value against the bird flu, or any others, in case patients ask. Pharmacognosy is not dead! Goodman PS. Star rises in fight against bird flu: Demand for a Chinese fruit skyrockets. *Washington Post.com* 2005 Nov 18; p. D01.

http://www.washingtonpost.com/wpdyn/content/article/2005/11/17/AR2005111701855.html?referrer=email

<u>Update</u> ...

Just received ...

• ACCP. *Directory of Residencies, Fellowships, and Graduate Programs 2006.* Kansas City, MO: American College of Clinical Pharmacy and the ACCP Research Institute.

AUBURN HSOP FACULTY in the literature ...

• Amato A, Marlowe K. Severe case of phenytoin-induced anticonvulsant hypersensitivity syndrome. *Am J Health-Syst Pharm*. 2005 Nov 1;62(21):2295-97.

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

• Baxter K, ed. *Stockley's Drug Interactions*. 7th ed. London: The Pharmaceutical Press, 2006.

TIMELY TOP TECH TIP ...

Pandemicflu.gov ... A web site to keep handy for yourself and patients. It's labeled as "The official U.S. government Web site for information on pandemic flu and avian influenza." Its general sections include: General Information, Health & Safety, Monitoring Outbreaks, Planning & Response Activities, Travel & Transportation, and Research Activities. There are also sections for News releases and highlights. Could be popular! www.pandemicflu.gov

The last "dose" ...



 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