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Key Inforbits

- Several MedWatch Alerts
- Influenza recommendations for 2006-2007
- STD treatment guidelines for 2006

- Guidelines for substance abuse treatments
- Several other guidelines have been published
- Social engineering?

NEW DRUGS, and other related stuff ...

MedWatch ... The FDA, the Federal Trade Commission (FTC), and the Centers for Disease Control and Prevention (CDC) alerted consumers about the facts surrounding the **direct-to-consumers marketing of genetic tests**. According to the FDA, which regulates the manufacturers of genetic tests, some of these tests lack scientific validity, and others provide medical results that are meaningful only in the context of a full medical evaluation. The FDA and CDC say that because of the complexities involved in both the testing and the interpretation of the results, genetic tests should be performed in a specialized laboratory, and the results should be interpreted by a doctor or trained counselor who understands the value of genetic testing for a particular situation.

Read the complete MedWatch 2006 Safety summary, including links to further FDA and FTC supporting information, at:

http://www.fda.gov/medwatch/safety/2006/safety06.htm#Genetic

MedWatch ... The Mentholatum Company and the FDA notified consumers and healthcare professionals about a nationwide recall of **WellPatch Cough & Cold Soothing Vapor Pads** due to potential serious adverse health effects that could result if the product is ingested by a child removing the patch and chewing it. This product contains camphor, eucalyptus oil, and menthol. Possible adverse events associated with chewing or ingesting products containing camphor or eucalyptus oils can vary from minor

chewing or ingesting products containing camphor or eucalyptus oils can vary from minor symptoms, i.e., burning sensation in the mouth, headache, nausea and vomiting, to more severe reactions such as seizures.

Read the complete MedWatch Safety summary, including a link to the firm press release, at; <u>http://www.fda.gov/medwatch/safety/2006/safety06.htm#WellPatch</u>

MedWatch ... Luitpold Pharmaceuticals, Inc. and FDA notified healthcare professionals of a **voluntary recall because some vials of Hydralazine HCl Injection** from lot number 5561 NO with an expiration date of December, 2006 (20 mg/mL, 1 mL single dose vials) may contain particulates. The lot is labeled with a NOVAPLUS label. Further use or distribution of this lot of product should cease.

Read the complete MedWatch 2006 Safety Summary, including a link to the Luitpold Pharmaceuticals, Inc., Recall Letter, at:

http://www.fda.gov/medwatch/safety/2006/safety06.htm#Hydralazine

MedWatch... The FDA announced that RoTech Healthcare, Inc., CCS Medical, and Reliant Pharmacy Services, are manufacturing and distributing nationwide, unapproved compounded inhalation drugs. These drugs, compounded by pharmacists, are used to treat life-threatening conditions such as asthma, emphysema, bronchitis, and cystic fibrosis. Compounded inhalation drugs are not reviewed by the FDA for safety and effectiveness and are often not produced according to good drug manufacturing practice, which may expose patients to unnecessary risks. FDA urges consumers using inhalation drugs to discuss their medications with their physicians and verify with their pharmacists that the medications they received are what their physicians ordered. FDA encourages patients to use FDA-approved drugs whenever possible. Read complete MedWatch 2006 Safety summary, including links to the FDA Press Release at: http://www.fda.gov/medwatch/safety/2006/safety06.htm#Inhalation

• On August 2, FDA approved first-time generic trimpiramine maleate to treat symptoms of depression. The Reference Listed Drug is Surmontil[®].

• On August 3, FDA approved first-time generic venlafaxine to treat depression. The Reference Listed Drug is Effexor[®].

• On July 28, FDA approved first-time generic finasteride to treat male pattern hair loss. The Reference Listed Drug is Propecia[®].

FROM THE MEDICAL LITERATURE ...

Recommendations for influenza, 2006-2007

and Prevention have issued their



... The Centers for Disease Control recommendations for the 2006-2007 formulation changes (different from

influenza season. In addition to the vaccine

last year), other changes include pediatric recommendations for children 6 to 59 months old, suggestions for caregivers and those planning vaccination campaigns, and a caution against using some of the oral antiviral treatments until susceptibilities are determined. For the entire 42-page report, go to the web site provided below.

ACIP. Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization practices (ACIP). MMWR. 2006 Jul 28;55(RR-10):1-42.

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm

Sexually Transmitted Diseases Treatment Guidelines, 2006 ... These guidelines have been updated by the Centers for Disease Control and Prevention from the last guideline report in 2002. There are a variety of updates included such as expanded diagnostic evaluations, new treatment recommendations, expanded discussions of several treatment protocols and STD prevention approaches. To see the complete 94-page report go to the web site provided below. Sexually transmitted diseases treatment guidelines, 2006. MMWR. 2006 Aug 4;55(RR11):1-94. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5511a1.htm

A-Fib Guidelines ... The American College of Cardiology, American Heart Association, and the European Society of Cardiology have published new clinical practice guidelines for managing patients with atrial fibrillation. It covers epidemiology and prognosis, pathophysiology as well as pharmacological and nonpharmacological management recommendations. The executive summary appears in August journal issues of the respective organizations, one of which is provided here.

ACC/AHA/ESC Writing Committee. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation - Executive summary. Circulation. 2006 Aug 15;114:700-752. http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.106.177031v1.pdf

Practice Guideline ... **Treatment of Patients with Substance Use Disorders**, 2nd ed, just published by the American Psychiatric Association. It is in three parts (A, B, C) and this guideline contains only Part A. The complete guideline, containing all three parts is available in print from the American Psychiatric Publishing, Inc (<u>http://www.psych.org</u>). Part A addresses treatment recommendations and covers general treatment principles, nicotine dependence, alcohol, marijuana, cocaine and opioid-related disorders.

Work Group on Substance Use Disorders. American Psychiatric Association Practice Guideline: Treatment of patients with substance use disorders, 2nd ed. *Am J Psychiatr*. 2006 Aug;163(8, Suppl):1-82.

Guidelines for Adult HIV Infection ... Emphasizes symptomatic and asymptomatic treatment, therapy guidelines, targets for monitoring and the importance of adherence, including continual reinforcement to the patient.

International AIDS Society-USA Panel. Treatment for adult HIV infection: 2006 recommendations of the International AIDS Society-USA Panel. *JAMA*. 2006 Aug 16;296(7):827-843.

ACIP Advisory Committee ... Prevention of Rotavirus Gastroenteritis Among Infants and

Children ... A primary recommendation is using the rotavirus vaccine (RotaTeq[®]) approved in February of this year. Although the virus is a cause of relatively few deaths in the U.S., the toll is much higher in developing countries. Also, it is a major cause of gastroenteritis in infants in the U.S. with nearly every child by the time they reach 5 years old, being infected. ACIP. Prevention of rotavirus gastroenteritis among infants and children: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2006 Aug 11;55(RR-12):1-16. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5512a1.htm

Reviews of Note ...

- Slørdal L, Spigset O. Heart failure induced by non-cardiac drugs. *Drug Safety*. 2006;29(7):567-86.
- Whyte MP. Paget's disease of bone. N Engl J Med. 2006 Aug 10;355(6):593-600.
- Sanfilippo A, English JC III. An overview of medicated shampoos used in dandruff treatment. *P&T*. 2006 Jul;31(7):396-400.

FROM THE LAY LITERATURE about medicine ...



Bad breath, or something else ... Article about the application of a relatively new technology of "edible film." Known to most people for use as a breath freshener, some drug products are being "pressed" into service. Some products currently available include some Triaminic[®] brands, Theraflu[®] and Gas-X[®] thin strips. These edible films could have wider application, particularly for the

young and elderly who may balk at swallowing some pills or liquids. They are also being employed for use in pets, who are masters of avoiding medication. The food industry is also experimenting with these strips to provide different flavors to some foods (eg, sushi). Weintraub A. It's on the tip of your tongue: As more medicines take the form of "edible film," the market is exploding. *BusinessWeek online*. 2006 Jul 31.

http://www.businessweek.com/magazine/content/06_31/b3995059.htm

Anniversary ... Legionnaires' Disease ... 1976 ... Late July marked the 30th anniversary of the "discovery" of a new disease, Legionnaires' Disease. It was so named because the initial recognized outbreak occurred at a Pennsylvania state American Legion convention in Philadelphia. *Legionella pneumophilia* was finally isolated from the hotel air conditioning system, but not before a number of men died. This article offers a brief, inside look at how events transpired 30 years ago.

Altman LK. In Philadelphia 30 years ago, an eruption of illness and fear. *New York Times*. 2006 Aug 1. http://www.nytimes.com/2006/08/01/health/01docs.html?_r=1&ref=health&oref=slogin

AUBURN HSOP FACULTY and STUDENTS in the literature ...

• Patel, Reena. Statins and diabetes mellitus: What's the answer? [letter] *P&T*. 2006 Jul;31(7):381-2

TIMELY TOP TECH TIP ...

Vocabulary ... **Social Engineering** ... A broad term that encompasses "phishing," primarily email messages created to induce the unwary to provide personal information that is in turn used to steal from them. In addition, unseen software may be deposited in your machine that will collect and send your every keystroke to those whom your best interest is <u>not</u> a priority. The emails are created to look like legitimate messages from respected institutions, many of which you may already have business dealings. Here are some tips:

- Do not trust email from financial institutions.
- Never respond to unsolicited commercial email or spam, or even click the link.
- Do not download or use free software unless you are sure it is from a trustworthy source.
- The best defense: Be smart, and careful!

Mossberg WS. Personal Technology: Some safety tips to help you avoid latest theft scams. Wall Street J. 2006 Jul 27; p. B1.

<u> The last "dose"</u> ...

-- Abbreviation for humorous misspelling, "oll korrect" [1838] For the history of this "most popular typical American expression," see Stuart Berg Flexner, / *Hear American Talking* [1976], pp. 261-262.

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Phone 334-844-4400 • Fax 334-844-8366 • <u>http://www.pharmacy.auburn.edu/dilrc/dilrc.htm</u> Bernie R. Olin, Pharm.D., Director