

AU InforMed

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Key Inforbits

- Cancer prevention vaccine approved!
- Old drugs flying under the radar?
- Eye drop reminder
- Swimmer's ear guidelines issued
- Sun protections - maybe
- Summer begins!

NEW DRUGS, and other related stuff ...

New Vaccine ... for Prevention of Cervical Cancer ... The FDA announced the approval of **Gardasil**[®], the first vaccine developed to prevent cervical cancer, precancerous and dysplastic genital lesions, and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18. The vaccine is approved for use in females 9-26 years of age. It is rated Pregnancy Category B and adverse effects are those expected from such injections. The dose is given in three separate injections at 0, 2 and 6 months. The product was evaluated and approved in six months under the FDA's priority review process.

<http://www.ptcommunity.com/Daily/DailyDetail.cfm?chosen=64687>

<http://www.gardasil.com/#> (Merck web site)

Available ... **Vivitrol**[™] (**naltrexone** for extended-release injectable suspension by Alkermes and Cephalon) for alcohol dependence, is now commercially available in the United States.

<http://www.ptcommunity.com/Daily/DailyDetail.cfm?chosen=64698>

<http://www.vivitrol.com/> (manufacturer web site)

New Indication ... The FDA has approved **bupropion HCL extended release tablets** (Wellbutrin XL[®]) as the first drug for prevention of major depressive episodes in patients with a history of seasonal affective disorder (SAD).

<http://www.ptcommunity.com/Daily/DailyDetail.cfm?chosen=64697>

Old Drugs ... The FDA is mad as hell, and they're not going to take it anymore! Although paraphrased from a famous movie line, it sums up recent FDA statements about unapproved drugs on the market. They seem to be getting serious about getting these drugs either off the market or through the proper channels, whatever it takes. Many of the drugs have been around a long time and have managed to stay below the regulatory radar.

FDA. Drugs marketed in the United States that do not have required FDA approval. FDA statement, June 8, 2006.

http://www.fda.gov/cder/drug/unapproved_drugs/default.htm

MedWatch ... The FDA notified healthcare professionals of the resumed marketing, with a special restricted distribution program of Tysabri[®] (natalizumab), a monoclonal antibody for the treatment of patients with relapsing forms of multiple sclerosis. Tysabri[®] was initially approved by the FDA in November 2004, but was withdrawn by the manufacturer in February 2005

after three patients in the drug's clinical trials developed progressive multifocal leukoencephalopathy (PML), a serious viral infection of the brain. Tysabri® will be available only through the Risk Management Plan, called the TOUCH Prescribing Program. Read the complete MedWatch 2006 Safety summary, including links to the Tysabri® Drug Information page and supporting documents, at:
<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Tysabri>

MedWatch ... FDA announced that it is evaluating safety information about **gadolinium-containing contrast agents** and Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/NFD) that occurs in patients with kidney failure. New reports have identified a possible link between NSF/NFD and exposure to high dose gadolinium containing contrast agents for Magnetic Resonance Angiography (MRA). The FDA has learned of 25 cases of NSF/NFD in patients with kidney failure who received Omniscan, a gadolinium-containing contrast agent, and took the MRA test. The FDA is investigating whether other patients who received gadolinium-containing contrast agents developed NSF/NFD. The FDA urges anyone to report adverse event information to the FDA online at <http://www.fda.gov/medwatch/report.htm>, by phone (1-800-FDA-1088) or by fax (1-800-FDA-0178). Read the complete MedWatch 2006 Safety summary, including links to the Public Health Advisory and supporting clinical information, at:
<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Gadolinium>

MedWatch ... Novartis Consumer Health, the sponsor, is conducting a nationwide voluntary recall of all **Triaminic Vapor Patch** products due to reports of serious adverse events associated with accidental ingestion by children. Triaminic Vapor Patch is labeled as a cough suppressant for children two years of age and older and is sold over the counter. Label directions indicate the patch is to be applied to the throat or chest to allow the vapors to reach the nose and mouth. FDA is warning consumers not to use the Triaminic Vapor Patch and is also advising consumers who have concerns or questions to contact their physician or health care practitioner. Read the complete MedWatch 2006 Safety summary, including links to the FDA Public Health Advisory and the firm's press release, at:
<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Triaminic>

FROM THE MEDICAL LITERATURE ...



HIV/AIDS Anniversary ... June 5, 1981 marks the first article describing here-to-fore rare cases of *Pneumocystis carinii* pneumonia in five California patients that later became recognized as cases of acquired immunodeficiency syndrome (AIDS).¹ Since then, it is estimated that 22 million people have died worldwide due to the disease. Currently over 1 million patients are living with HIV/AIDS in the U.S. and up to 40,000 new cases are expected to arise this year. The CDC has published a special issue of *MMWR* to once again focus attention on the problem.²

¹CDC. *Pneumocystis pneumonia* – Los Angeles. *MMWR*. 1981 Jun 5;30(21):250-2.

²CDC. Twenty-five years of HIV/AIDS – United States, 1981-2006. *MMWR*. 2006 Jun 2;55(21):585-9.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5521a1.htm>



Reminder ... from the *Medical Letter* about the use of **eye drops**. The article reminds us that although a drop can vary greatly in size (35-75 microliters, avg. 35-50 microliters), the eye can hold only about 30 microliters. Therefore, anything more than one drop will either contribute to toxicity or be washed away. If two different drops are being used, separate the two instillations by 5 minutes. Abramowicz M, ed. One drop or two? *Med Lett Drugs Ther*. 2006 Jun 19;48(1237):49.



Just in time for summer ... and swimmers ear, the first **clinical practice guidelines** published for Acute Otitis Externa, by the American Academy of Otolaryngology-Head and Neck Surgery Foundation, Inc, emphasizing diagnosis, use of systemic and topical antibiotics and proper counseling in their use. In the same supplement, there is a systematic review of topical antimicrobial therapy for Acute Otitis Externa. They are effective!

Rosenfeld RM, Brown L, Cannon CR, Dolor RJ, Ganiats TG, Hannley M, et al. Clinical practice guideline: Acute otitis externa. *Otolaryngol Head Neck Surg.* 2006;134(Suppl):S4-S23.

Rosenfeld RM, Singer M, Wasserman JM, Stinnett SS. Systematic review of topical antimicrobial therapy for acute otitis externa. *Otolaryngol Head Neck Surg.* 2006;134(Suppl):S24-S48.

Reviews of Note ...

- Katon WJ. Panic disorder. *N Engl J Med.* 2006 Jun 1;354(22):2360-7.
- Chen JJ, Ly A-V. Rasagiline: A second-generation monoamine oxidase type-B inhibitor for the treatment of parkinson's disease. *Am J Health-Syst Pharm.* 2006 May 15;63(10):915-28.
- Koleba T, Ensom MHH. Pharmacokinetics of intravenous immunoglobulin: A systematic review. *Pharmacotherapy.* 2006 Jun;26(6):813-27.
- Woo S-B, Hellstein JW, Kalmar JR. Systematic review: bisphosphonates and osteonecrosis of the jaws. *Ann Intern Med.* 2006 May 16;144:753-61.
- Dunn C, Curran MP. Inhaled human insulin (Exubera): A review of its use in the adult patients with diabetes mellitus. *Drugs.* 2006;66(7):1013-32.
- Watts DH. Treating HIV during pregnancy: An update on safety issues. *Drug Safety.* 2006;29(6):467-90.
- Kamel NS, Gammack JK. Insomnia in the elderly: Cause, approach, and treatment. *Am J Med.* 2006 Jun;119(6):463-9.

FROM THE LAY LITERATURE about medicine ...



Super-organism ... That is a description of us, when viewed as a collection of human cells (10%) and bacterial cells (90%). A group inspected the human gut for the collection of microorganisms and analyzed the collective genome, the "microbiome," and found at least 100x as many genes as the human genome. It is estimated the microbiota is composed of 10^{13} to 10^{14} microorganisms, and collectively weighs about 3 pounds. Lots of fun facts and figures for that next party conversation. The simple version (*Washington Post*)¹ and the original (*Science*)² references are provided.

¹Weiss R. Legion of little helpers in the gut keeps us alive. *Washington Post.* 2006 Jun 5; p. A06.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/06/04/AR2006060400603.html?referrer=email>

²Gill SR, Pop M, DeBoy RT, Eckbury PB, Turnbaugh PJ, Samuel BS, et al. Metagenomic analysis of the human distal gut microbiome. *Science.* 2006 Jun 2;312:1355-9.

Impact Factor ... Sigh. The "impact factor" is a proprietary rating that attempts to determine the "importance" of journals to the scientific community by counting and calculating the number of times articles from a journal are cited by others. In some academic circles the impact factor is given great weight when considering promotion and tenure. A recent article has revealed how some journals attempt to manipulate data, by encouraging self-citation, or discouraging citation of competitor journals, to boost their impact factor. There are, of course, denials all around.

Begley S. Science journals artfully try to boost their rankings. *Wall Street Journal.* 2006 Jun 5; p. B1.



Sun protection ... a short, but interesting article about some of the “less well established” products being promoted for sun protection. These include herbal supplements (although labeling also encourages sunscreen), sensors to stick to skin to say “enough!”, electronic devices to “analyze” your UV exposure, and weight-loss sunscreen, rub it on to get sun protection and watch the weight melt away! To quote the author here, “if only.”

Huget J. New sun protection products stretch the imagination. *Washington Post*. 2006 Jun 13; p. HE06.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/06/12/AR2006061201106.html?referrer=email>

NEW RESOURCES in the DILRC ...

- Skidmore-Roth L. *Mosby's Handbook of Herbs & Natural Supplements*. 2nd ed. St. Louis: Mosby/Elsevier, 2004.
- Posey LM. *Pharmacy: An Introduction to the Profession*. Washington, DC: American Pharmacists Association, 2003.
- Gourley DR, ed. *The APhA Complete Review for Pharmacy*. 3rd ed. Washington, DC: American Pharmacists Association, 2005.

AUBURN HSOP FACULTY and STUDENTS in the literature ...

- Baldwin JN, Jungnickel PW. Alcoholism. In: RA Helms, DJ Quan, ET Herfindal, DR Gourley, eds. *Textbook of Therapeutics: Disease and Drug Management*, 8th ed. Baltimore: Lippincott, Williams & Wilkins, 2006;1515-1536.
- Wargo KA, McConnell VJ, Higginbotham SA. A case of *Streptococcus intermedius* empyema. *Ann Pharmacother*. 2006 Jun;40:1208-10.
- Fagan NL, Wargo KA, Malone PM, Malesker MA. The clinical utility of clonidine. *US Pharmacist*. 2006 May;31:HS2-HS16.



The last “dose” ...



“Summertime
And the livin' is easy”
-- Porgy and Bess [1935] Summertime
Ira Gershwin [1896 - 1983]

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