

AU InforMed

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Key Inforbits

- Bird Flu vaccine and a new ointment
- Bad news for chondroitin
- Age management and lifestyle medicine
- No free lunch
- Pharmacist satisfaction survey published
- Gone, but not completely!

NEW DRUGS, and other related stuff ...

Bird Flu Vaccine ... (4/17/2007) The FDA announced the first approval in the US of a vaccine for humans against the H5N1 influenza virus, commonly known as avian or bird flu. The vaccine could be used in the event the current H5N1 avian virus were to develop the capability to efficiently spread from human to human, resulting in a global pandemic. Should such an influenza pandemic emerge, the vaccine may provide early limited protection in the months before a vaccine tailored to the pandemic strain of the virus could be developed and produced. Unlike seasonal influenza, where infection ranges from mild to serious symptoms in most people, the disease caused by H5N1 is far more severe and happens quickly, with pneumonia and multi-organ failure commonly seen.

While there have been no reported human cases of H5N1 infection in the US, almost 300 people worldwide have been infected with this virus since 2003 and more than half of them have died. The manufacturer, Sanofi Pasteur Inc., will not sell the vaccine commercially. Instead, the vaccine has been purchased by the federal government for inclusion within the U.S. Strategic National Stockpile for distribution by public health officials if needed. The approval and availability of this vaccine will enhance national readiness and the nation's ability to protect those at increased risk of exposure. The U.S. Strategic National Stockpile is maintained by the U.S. Centers for Disease Control and Prevention. It contains large quantities of medicine and medical supplies to protect the American public if there is a public health emergency, which can be delivered to any state in the United States within 12 hours. For more information on the government's preparedness efforts, visit: www.pandemicflu.gov.

FDA approves first U.S. vaccine for humans against the avian influenza virus H5N1. *FDA News*. 2007 Apr 17; P07-68. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01611.html>

New Drug ... (4/13/2007) The FDA has approved **retapamulin ointment (Altabax™** by GlaxoSmithKline) for topical treatment of impetigo. Altabax™ is indicated for use in patients aged nine months or older. Altabax™ was approved on the basis of efficacy data from a placebo-controlled study supported by a study comparing Altabax™ to another antibiotic. The safety database contained approximately 2,000 Altabax™-treated adults and children aged nine months and older, and about 1,000 similar patients who received different antibiotics or placebo. The most common Altabax™-related adverse event was irritation at the site of the application, which occurred in less than 2% of the patients. This product will be available by prescription.

FDA approves antibiotic ointment for children and adults. *FDA News*. 2007 Apr 13; P07-65.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01607.html>

http://us.gsk.com/products/assets/us_altabax.pdf [GSK package labeling]

New Biologic ... (3/30/2007) The FDA has licensed **protein C concentrate (human)** (**Ceprotrin** by Baxter Healthcare Corp), the first biologic treatment for patients with a rare genetic defect, severe congenital protein C deficiency. Ceprotrin is made from the plasma of healthy human blood donors. It is a concentrated form of protein C, a substance normally manufactured in the liver that circulates in the plasma in very small amounts. Protein C plays an important role in controlling blood coagulation by preventing the formation and growth of blood clots. Severe congenital protein C deficiency is a rare genetic defect found in one to two newborns for every million births. Patients with insufficient levels of protein C experience abnormally high numbers of blood clots. Complete absence of the protein is fatal. Symptoms typically appear soon after birth. Clotting may occur throughout the body. Patients with severe inherited protein C deficiency must take anticoagulant drugs on a regular basis to avoid blood clots. Ceprotrin is intended to treat these patients when they are faced with a life-threatening situation from blood clots in the veins, or a severe skin and systemic blood clotting disorder known as Purpura fulminans. FDA granted Ceprotrin orphan drug status.

FDA approves first biologic to treat rare clotting disorder. *FDA News*. 2007 Mar 30; P07-56.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01598.html>

MedWatch ... (4/11/2007) Acorda Therapeutics and the FDA informed healthcare professionals of changes to the CONTRAINDICATIONS and WARNINGS Sections of the product labeling for **Zanaflex (tizanidine)**, a drug used to treat spasticity. In pharmacokinetic studies where tizanidine was coadministered with either fluvoxamine or ciprofloxacin (CYP1A2 inhibitors), the serum concentration of tizanidine was significantly increased and potentiated its hypotensive and sedative effects. Although there are no clinical studies evaluating the effects of other CYP1A2 inhibitors on tizanidine, coadministration of tizanidine with other CYP1A2 inhibitors (zileuton, other fluoroquinolones, antiarrhythmics, cimetidine, famotidine, oral contraceptives, acyclovir and ticlopidine) should be avoided.

Read the complete MedWatch 2007 Safety summary, including a link to the manufacturer's Dear Healthcare Provider Letter regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Zanaflex>

FROM THE MEDICAL LITERATURE ...

More bad news for natural products ... In yet another study done in a major medical journal, natural therapies did not prove beneficial. In this case it was a meta-analysis of chondroitin for osteoarthritis of the knee or hip. A thorough search located 20 trials (total of 3846 patients) that were quite heterogenous. The smaller, less rigorous and not analyzed using the intention-to-treat principle showed the best effects for chondroitin. The largest, most methodologically sound trials showed virtually no benefit with the use of chondroitin. However, an accompanying editorial, while pointing out some limitations of this meta-analysis, makes the point that if patients perceive a benefit with little demonstrated harm, why not use it?

Reichenbach S, Sterchl R, Scherer M, Trelle S, Bürgi E, Bürgi U, et al. Meta-analysis: Chondroitin for osteoarthritis of the knee or hip. *Ann Intern Med*. 2007 Apr 17;146:580-590.

Felson DT. Chondroitin for pain in osteoarthritis. *Ann Intern Med*. 2007 Apr 17;146:611-612.



Reviews of Note ...

- Nathan N, Odin I. Induction of anaesthesia: A guide to drug choice. *Drugs*. 2007;67(5):701-723.

- Chidlow G, Wood JPM, Casson RJ. Pharmacological neuroprotection for glaucoma. *Drugs*. 2007;67(5):7025-759.
- Smith HS, ed. Pain Management, Part II. *Med Clin N Am*. 2007 Mar;91(2):177-320. (9 articles)
- Way CM. Safety of newer antidepressants in pregnancy. *Pharmacotherapy*. 2007 Apr;27(4):546-552.
- Pham AQ, Kourlas H, Pham DQ. Cinnamon supplementation in patients with type 2 diabetes mellitus. *Pharmacotherapy*. 2007 Apr;27(4):595-599.

FROM THE LAY LITERATURE about medicine ...

Vocabulary ... Age management ... Not a recognized medical specialty, but they have their own organization, The American Academy of Anti-Aging Medicine (A4M). It includes many recognized concepts such as supplements, diets, and exercise. Also, the practitioner interviewed, Dr. Ana Casas, practices “concierge medicine,” that is patients have full access for all the time they need, including the physician’s email and cell phone – and, no waiting, all for a sizeable retainer fee,. Appointments may last 2 to 4 hours. However, even Dr. Casas says that “age management is preventive medicine.” The wellness concept raises its head, again.



Hellerman C. ‘Age management’ is a controversial new medical focus. *CNN.com*. 2007 Apr 6.
<http://www.cnn.com/2007/HEALTH/04/06/chasing.antiaging.med/index.html>

Vocabulary ... Lifestyle Medicine ... related to “age management” above. A fledgling organization, the American College of Lifestyle Medicine, has been formed to emphasize the importance of lifestyle (eg, diet, exercise, sleep, stress management) in preventing and treating disease; it is actively recruiting various specialties into their ranks. They have a journal, *The American Journal of Lifestyle Medicine* and they are looking to create a certification process. This seems like a no-brainer, but perhaps health professionals will take notice if there is an “official” organization promoting the agenda. Little else has seemed to work, so far.

Murphy K. Teaching doctors to teach patients about lifestyle. *New York Times*. 2007 Apr 17.
<http://www.nytimes.com/2007/04/17/health/17life.html? r=1&ref=health&oref=slogin>



If you are looking for a physician unencumbered by industry influence, here is a way to find them. A grassroots group of health professionals called “No Free Lunch” was formed to try to reduce pharmaceutical industry influence on medical practice. The members in the non-profit group’s database have pledged not to take “money, gifts or hospitality” from drug companies and to make medical decisions based on the best evidence available. The group points out that research has shown that even small gifts can influence physician behavior. Dr. Bob Goodman, founder of No Free Lunch, says that the [directory](#) “will help patients and could attract attention to the issue.” Most of the listed physicians are internists and family practitioners. It is free and covers the U.S. but has only 500 participants to date, so they are few and far between. One responder to the health blog, a physical therapist, reported that his efforts to meet with physicians to drum up business was met with demands for free lunch for the entire staff before they would even consider his request for a meeting. As reported earlier, it is apparently the new currency. Hensley S. No free lunches for these docs (Blog report). *Wall Street Journal* 2007 Apr 16.

Pharmacy satisfaction survey ... (4/17/2007) J.D. Powers and Associates has conducted an inaugural study measuring customer satisfaction with retail pharmacies, brick-and-mortar as well as on-line. The biggest factor affecting customer satisfaction was the pharmacy staff asking the patient if they would like to speak to the pharmacist! This simple act went a long way to solidify satisfaction. Not all patients want to speak to the pharmacist, but it exhibits concern for their well-being which goes a long way. Rankings of pharmacies are also provided in the categories of retail chain; supermarkets; mass merchandiser and mail order. See web sites below for data.
<http://www.jdpower.com/press-releases/pressrelease.aspx?id=2007057> [Press Release and data]
<http://www.jdpower.com/healthcare/ratings/pharmacy/> [Individual Rankings by Category]

AUBURN HSOP FACULTY in the literature ...

- **Carroll DG, Cavanagh LE.** Drug-induced lupus associated with synthetic conjugated estrogens. *Ann Pharmacother.* 2007 Apr;41:702-706.

NEW RESOURCES in the DILRC ...

- **NCPA-Pfizer Digest ...** The latest NCPA-Pfizer Digest is now available, covering the year 2005. It provides some financial overviews of community pharmacy and several stories on “showcase” community pharmacy practices. One copy is available in the DIC. It may also be available from a Pfizer representative and for sale through the NCPA.. West DS, ed. The face of independent pharmacy Alexandria, VA: National Community Pharmacists Association.. NCPA-Pfizer Digest, 2006.
- **Gourley DR, Eoff JC III, eds.** The APhA Complete Review for Pharmacy. 4th ed. Washington, DC: American Pharmacists Association, 2007.

TIMELY TOP TECH TIP ...

‘Deleted’ but still accessible ... Just a reminder, particularly for email, they are VERY hard to eliminate! Many people have regretted the push of the send button for ill chosen words (“if you don’t want to see it on ‘60 Minutes’, don’t send it!”), but as some of our federal officials are finding out, again, there can be serious ramifications! This article gives an idea why those emails are so hard to completely delete (they don’t just live on two computers) and some idea of what to do about it. -*Caveat Sendor*-

Pegoraro R. ‘Delete’ doesn’t mean ‘disappear.’ *Washington Post.* 2007 Apr 14; p. D01.
<http://www.washingtonpost.com/wp-dyn/content/article/2007/04/13/AR2007041301913.html?referrer=email>



The last “dose” ...

“Moderation in all things.”

-- Terence [Publius Terentius Afer] c. 190-159 B.C.
from *Andria* (The Lady of Andros), l. 61

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