AU InforMed

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Key Inforbits

- Many MedWatches!
- Coffee good for gout
- You can't say that anymore …
- Survivorship
- PSA explained, simply
- The soldier

NEW DRUGS, and other related stuff …

New Drug Product … (5/22/2007) The FDA approved **Lybrel™** (by Wyeth), the first continuous use drug product for prevention of pregnancy. It comes in a 28 day-pill pack with low-dose combination tablets that contain 90 micrograms of a progestin, levonorgestrel, and 20 micrograms of an estrogen, ethinyl estradiol, which are active ingredients available in other approved oral contraceptives. Continuous contraception works the same way as the 21 days on-seven days off cycle. It stops the body's monthly preparation for pregnancy by lowering the production of hormones that make pregnancy possible. Other contraceptive pill regimens have placebo or pill-free intervals lasting four to seven days that stimulate a menstrual cycle. Lybrel™ is designed to be taken without the placebo or pill-free time interval. Women who use Lybrel™ would not have a scheduled menstrual period, but will most likely have unplanned, breakthrough, unscheduled bleeding or spotting. Because Lybrel™ users will eliminate their regular periods, it may be difficult for women to recognize if they have become pregnant. Women should take a pregnancy test if they believe they may be pregnant.

FDA approves contraceptive for continuous use. *FDA News*. 2007; P07-89.
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01637.html

Unapproved Drug … **Guaifenesin** … (5/25/07) The FDA announced its intention to take action against companies that market unapproved drug products in timed-release dosage form that contain guaifenesin. Approximately 20 firms make timed-release products containing guaifenesin that have not undergone FDA review and are unapproved drugs. This action does not affect products containing guaifenesin in immediate release form. Many of the products that contain guaifenesin also contain other active ingredients that are intended to relieve nasal congestion, suppress cough, reduce fever or relieve pain. To date, only Adams Respiratory Therapeutics has obtained FDA approval for timed-release products containing guaifenesin (600 mg and 1200 mg) under the trade names of Mucinex and Humibid. These include over-the-counter products containing guaifenesin alone (Mucinex and Humibid), with the decongestant pseudoephedrine (Mucinex-D), and with the cough suppressant dextromethorphan (Mucinex-DM). Companies marketing unapproved products containing guaifenesin in timed-release form are to stop manufacturing them within 90 days and cease shipping them in interstate commerce within 180 days.

FDA's Unapproved Drugs Web site:
http://www.fda.gov/cder/drug/unapproved_drugs/default.htm.

FDA takes action to stop marketing of unapproved timed-release guaifenesin drug products. *FDA News*. 2007 May 25; P07-92.
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01640.html

Product Recall … **Complete MoisturePlus Multi Purpose Solution contact lens solution** … The FDA is alerting health care professionals and their patients who wear soft contact lenses about a **voluntary recall of Complete MoisturePlus Multi Purpose Solution** manufactured by Advanced Medical Optics of Santa Ana, CA. The company is taking this action as a precaution because of reports of a rare, but serious, eye infection, ***Acanthamoeba* keratitis**, caused by a parasite. The link between the solution and the infection was identified by the Centers for Disease Control and Prevention (CDC). Consumers who wear soft contact lenses should stop using the solution, discard all partially-used or unopened bottles and replace their lenses and storage container. *Acanthamoeba* keratitis may lead to vision loss with some patients requiring a corneal transplant. The infection primarily affects otherwise healthy people who wear contact lenses. Consumers should ask their doctor about alternative cleaning/disinfecting products and seek immediate treatment if they have symptoms of eye infection. The symptoms of *Acanthamoeba* keratitis can be very similar to those of other more common eye infections and may include eye pain or redness, blurred vision, light sensitivity, sensation of something in the eye or excessive tearing but *Acanthamoeba* is more difficult to treat. Additional information regarding the CDC results is available at the CDC website http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d526a1.htm.
The bulletin also reminds contact lens users of general precautions to help prevent eye infections. Additional information about *Acanthamoeba* infection is available from the CDC website at http://www.cdc.gov/ncidod/dpd/parasites/acanthamoeba/index.htm.
Firm Press Release (May 25, 2007)
Advanced medical optics voluntary recalls Complete MoisturePlus contact lens solution. *FDA News*. 2007 May 26; P07-93.
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01641.html

MedWatch … (5/21/2007) The FDA informed healthcare professionals of a potential **safety issue related to Avandia (rosiglitazone)**. An on-going analysis of safety data for the treatment of type 2 diabetes mellitus using Avandia showed differing rates of ischemic cardiovascular events including heart attack or heart-related adverse events, some fatal, relative to other drugs used to treat diabetes. The clinical studies reviewed to date vary with respect to their populations, treatment regimens, and length of follow-up. Based on these data, the risk of ischemic cardiovascular events due to Avandia remain unclear. Prescribers should continue to carefully make individualized treatment decisions for patients with diabetes mellitus.
Read the complete 2007 Safety Summary, including a link to the FDA News Release and Prescribing Information regarding is issue at:
http://www.fda.gov/medwatch/safety/2007/safety07.htm#Avandia
This report is based on early release articles from the *New England Journal of Medicine*, first reported last week: Both are available at www.nejm.org and will be published June 14.
Nissen SE, Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *N Engl J Med*. 2007 May 21;356:10.1056/NEJMoa072761.
Psaty BM, Furberg CD. Rosiglitazone and cardiovascular risk. *N Engl J Med*. 2007 May 21;356:10.1056/NEJMe078099.

MedWatch … (5/22/2007) Novartis and the FDA notified healthcare professionals of changes to the WARNINGS and ADVERSE REACTIONS sections of the product labeling for **Exjade (deferasirox)**, a drug used to treat chronic iron overload due to blood transfusions (transfusional hemosiderosis). **Cases of acute renal failure**, some fatal, have been reported. Most of the fatalities occurred in patients with multiple co-morbidities and who were in advanced stages of their hematological disorders. Additionally, there were post marketing reports of cytopenias, including agranulocytosis, neutropenia and thrombocytopenia in some patients. The relationship

of these episodes to treatment with Exjade is uncertain. Most of these patients had preexisting hematologic disorders that are frequently associated with bone marrow failure. Further, cases of leukocytoclastic vasculitis, urticaria, and hypersensitivity reactions (including anaphylaxis and angioedema) were reported. Healthcare professionals should monitor serum creatinine in patients who are at increased risk of complications, having preexisting renal conditions, are elderly, have co-morbid conditions, or are receiving medicinal products that depress renal function. Blood counts should also be monitored regularly and treatment should be interrupted in patients who develop unexplained cytopenia.
Read the complete 2007 Safety Summary, including a link to the Manufacturer's Dear Healthcare Professional Letter regarding this issue at:
http://www.fda.gov/medwatch/safety/2007/safety07.htm#Exjade

MedWatch … (5/22/2007) The FDA announced a request for the addition of a boxed warning and new warnings about the risk of **nephrogenic systemic fibrosis (NSF)** to the full prescribing information for all **gadolinium-based contrast agents** (GBCAs). The new prescribing information FDA is requesting highlights and describes the risk for NSF following exposure to a GBCA in patients with acute or chronic severe renal insufficiency (glomerular filtration rate <30 mL/min/1.73 m^2) and patients with acute renal insufficiency of any severity due to the hepato-renal syndrome or in the peri-operative liver transplantation period. Healthcare professionals should avoid the use of a GBCA in these patients unless the diagnostic information is essential and not available with non-contrast enhanced magnetic resonance imaging.
Read the complete 2007 Safety Summary, including a link to the FDA Healthcare Professional Sheet, FDA News Release, and Q & A Document regarding this issue at:
http://www.fda.gov/medwatch/safety/2007/safety07.htm#Gadolinium

FROM THE MEDICAL LITERATURE …

Coffee … **good for gout** … A prospective, observational study of 45,869 health professional men with no history of gout was conducted to assess the effects of coffee consumption on gout development. Using a validated questionnaire covering diet, medical history and medications, assessments were made over a 12 year period. Outcomes revealed that the development of gout in the most common population (males >40 years old) was inversely proportional to the amount of coffee consumed. Greater than 6 cups of coffee daily had the greatest benefit. This effect was similar, though not quite so dramatic, with decaffeinated coffee. The original speculation was that caffeine was the "active" ingredient for this effect, but other sources of caffeine (eg, tea) did not appear to confer benefit. The author's conclusion, in this restricted population group, is that long term coffee consumption lowers the risk of development of gout.

Choi HK, Willett W, Curhan G. Coffee consumption and risk of incident gout in men: A prospective study. *Arthritis Rheum*. 2007 Jun;56(6):2049-2055.

Three phrases on health care that cannot be said on TV … An editorial speaking to the "new era" of health care and how we got here. Three phrases that used to be accepted as common knowledge now have serious reservations. "Best health care system in the world" was commonly accepted of the U.S. health care system. This has been called into question; most expensive system, yes, but world comparative data on such measures as life expectancy and infant mortality show that all of our money isn't buying much. "Health care is special" is another questioned phrase. Health care was once considered outside of the realm of normal economics and that nothing was to be spared when treating a patient. That changed a few

years ago when patients began to have to make choices between very expensive drugs and groceries. "New is better" is the last unutterable phrase. There are many examples of "breakthroughs" just breaking, eg, Vioxx®, metal and drug-coated stents, SSRI's for adolescents, and erythropoietin for anemia. Makes you think, where are we headed?
Emanuel EJ. What cannot be said on television about health care. *JAMA*. 2007 May 16;297(19):2131-2133.

Reviews of Note …

- Griffith KS, Lewis LS, Mali S, Parise ME. Treatment of malaria in the United States. *JAMA*. 2007 May 23/30;297(20):2264-2277.
- DeMaria EJ. Bariatric surgery for morbid obesity. *N Engl J Med*. 2007 May 24;356(21):2176-2183.

FROM THE LAY LITERATURE about medicine …

Vocabulary … **Survivorship** … is an emerging medical specialty aimed at the growing number of cancer survivors. It is estimated that 80% of patients treated for cancer will be long term survivors. This raises issues of how to deal with the longer term adverse effects of cancer chemotherapy/radiation therapy, other organ systems that may have been damaged during therapy, psychological effects of the disease and therapy, and just general health issues that may or may not need to be put in the context of previous cancer treatment. These patients may need an extra measure of understanding and something more than, "just be glad you survived."
Berger L. Cancer care seeks to take patients beyond survival. *New York Times*. 2007 May 22.
http://www.nytimes.com/2007/05/22/health/22canc.html?ref=health

PSA confusing? … Have you been confused about the prostate specific antigen test? What is good, what is not? What does it all mean, anyway? Leave it to a newspaper article to clear it up.

The author does a nice job of sorting out some of the issues with the PSA and its significance. There is some discussion of test interference, the confusion in the medical community and some interesting statistics. Also, new guidelines are coming.
Brody JE. Deciphering the results of a prostate test. *New York Times*. 2007 May 8.
http://www.nytimes.com/2007/05/08/health/08brod.html?_r=1&oref=slogin&pagewanted=print

The last "dose" …

"It is the Soldier, not the reporter, who has given us freedom of the press. It is the Soldier, not the poet, who has given us freedom of speech. It is the Soldier, not the campus organizer, who has given us freedom to demonstrate. It is the Soldier, not the lawyer, who has given us the right to a fair trial. It is the Soldier, who salutes the flag, who serves beneath the flag, and who's coffin is draped by the flag, who allows the protester to burn the flag"
-- Father Dennis Edward O'Brien/USMC [1923 – 2002]

An electronic bulletin of drug and health-related news highlights, a service of …
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