AU InforMed

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Key Inforbits

- Questionable utility of pharmacy labels
- Serious ADE's are on the rise
- Cold & Cough meds pulled from shelves
- The "Wal-Mart effect"
- Microsoft "Health Vault"
- Wish of a wise man …

NEW DRUGS, and other related stuff …

New Drug … (10/12/2007) The FDA has granted **raltegravir (Isentress™ tablets by Merck)** accelerated approval for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. Isentress™ is the first approved integrase inhibitors, a new class of antiretroviral drugs. It works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme which limits the ability of the virus to replicate and infect new cells. The FDA's decision was based on a 24-week analysis of clinical trials in which Isentress™ in combination with optimized background therapy in treatment-experienced patients, provided significant reductions in HIV RNA viral load and increases in CD4 cell counts. Longer term data are required before the FDA can consider traditional approval for Isentress™.

FDA Approves ISENTRESS™ (raltegravir) Tablets, First-in-Class Oral HIV-1 Integrase Inhibitor. Press Release. Merck & Co, Inc. 2007 Oct 12.

http://www.merck.com/newsroom/press_releases/product/2007_1012.html

http://www.isentress.com/raltegravir/isentress/index.jsp [Merck web site for Isentress™]

New flu vaccine … (9/28/2007) The FDA has approved **Afluria™ (an additional seasonal influenza vaccine by CSL Limited of Parkville, Australia)** for the immunization of people ages 18 and older. Afluria™ is intended to protect adults from influenza type A and type B flu viruses. The approval of Afluria™ brings the number of seasonal influenza manufacturers licensed for the U.S. market to six. The Centers for Disease Control and Prevention (CDC) estimates that the six manufacturers will supply a record 132 million doses of influenza vaccine for the 2007-2008 influenza season. Flu season in the U.S. ranges from October to May. Every year in the U.S., more than 200,000 people are hospitalized with influenza and about 36,000 people die from its complications. Afluria™ contains inactivated influenza viruses grown in chicken eggs. People who are allergic to eggs or any other component of the vaccine should not receive Afluria™.

http://www.fda.gov/bbs/topics/NEWS/2007/NEW01714.html

New Combination … (9/28/2007) **Azor™ (amlodipine and olmesartan medoxomil**, by Daiichi-Sankyo) has been approved for the treatment of hypertension, alone and with other antihypertensive agents. It carries a pregnancy category of C in the first trimester and D in the second and third trimesters. http://www.azor.com/

MedWatch … (10/12/2007) The FDA has received reports of deaths and serious cardiopulmonary reactions following administration of ultrasound micro-bubble contrast agents used in echocardiography. Four of the 11 reported deaths were caused by cardiac arrest occurring either during infusion or within 30 minutes following the administration of the contrast agent. Most of the serious but non-fatal reactions also occurred in this time frame. To optimize their safe use, the manufacturers of Definity and Optison are revising the labeling. Revised labeling includes a statement in the INDICATIONS section cautioning that the safety and efficacy of the use of Definity with exercise or pharmacological stress testing have not been established. These labeling changes emphasize the risk for serious cardiopulmonary reactions, and that the use of these products is contraindicated in patients with unstable cardiopulmonary status, including patients with unstable angina, acute myocardial infarction, respiratory failure, or recent worsening congestive heart failure.
Read the complete MedWatch 2007 Safety Summary, including a link to the Drug Information Page, at: http://www.fda.gov/medwatch/safety/2007/safety07.htm#bubble

MedWatch … (10/16/2007) The FDA has reviewed 30 postmarketing reports of **acute pancreatitis in patients taking Byetta (exenatide)**, a drug used to treat adults with type 2 diabetes. Amylin Pharmaceuticals, Inc. has agreed to include information about acute pancreatitis in the PRECAUTIONS section of the product label. Healthcare professionals should be alert to the signs and symptoms of acute pancreatitis and instruct patients taking Byetta to seek prompt medical care if they experience unexplained, persistent, severe abdominal pain with or with out vomiting. If pancreatitis is suspected, Byetta should be discontinued. If confirmed, Byetta should not be restarted unless an alternative etiology is identified.
Read the complete MedWatch 2007 Safety Summary including a link to Information for Healthcare Professionals, at: http://www.fda.gov/medwatch/safety/2007/safety07.htm#Byetta

FROM THE MEDICAL LITERATURE …

Pharmacy labels … **self-promotion vs. instructional** … A multi-city (Chicago, Boston, Los Angeles and Austin) prescription label study was conducted at 2 chain, grocery, and independent pharmacies. These pharmacies were asked to fill 85 prescriptions for four commonly used medications (atorvastatin, alendronate, trimethoprim-sulfamethoxazole, and ibuprofen). This study revealed that patient information seemed to take a back seat to the pharmacy name and information when it came to instruction and emphasis. The actual patient instructions were consistent and average point size was 9.3. However, the warning stickers accompanying the label were an average of 6.5 point and the information was quite variable.

Shrank WH, Agnew-Blais J, Choudhry NK, Wolf MS, Kesselheim AS, Avorn J, Shekelle P. The variability and quality of medication container labels. *Arch Intern Med*. 2007 Sep 10;167(16):1760-1765.

Increased serious ADEs … A study of the U.S. Food and Drug Administration's (FDA) Adverse Event Reporting System revealed that through 1998-2005, serious adverse drug events increased 2.6-fold from 34,966 to 89,842. Fatal adverse drug events increased 2.7-fold from 5519 to 15,107. In addition, only about 20% of drugs accounted for 87% of the adverse events reported; also 87% of reports were not mentioned on the drugs' respective labels. One reason given for the increase was simply more reports due to health professionals' greater sensitivity to the problem (due to some high profile drug problems); there could be many others.
Moore TJ, Cohen MR, Furberg CD. Serious adverse drug events reported to the Food and Drug Administration, 1998-2005. *Arch Intern Med*. 2007 Sep 10;167(16):1752-1759.

Reviews of Note …

- Lane NE. Osteoarthritis of the hip. *N Engl J Med*. 2007 Oct 4;357(14):1413-1421.
- Feder HM Jr, Johnson BJB, O'Connell S, Shapiro ED, Steere AC, Wormser GP and the Ad Hoc International Lyme Disease Group. A critical appraisal of "chronic lyme disease." *N Engl J Med*. 2007 Oct 4;357(14):1422-1430.
- Roberts DM, Buckley NA. Pharmacokinetic considerations in clinical toxicology: Clinical applications. *Clin Pharmacokinet*. 2007;46(11):897-939.
- Yang LPH, Keam SJ, Keating GM. Deferasirox: A review of its use in the management of transfusional chronic iron overload. *Drugs*. 2007;67(15):2211-2230.
- Guindon J, Walczak J-S, Beaulieu. Recent advances in the pharmacological management of pain. *Drugs*. 2007;67(15):2121-2133.

FROM THE LAY LITERATURE about medicine …

Cough and Cold meds pulled from shelves … The FDA will be reviewing labeling for many over-the-counter (OTC) cough/cold products in a meeting this week. Their review of adverse event reports over the last four decades overdoses and fatalities in children. Children under 2 years seem most susceptible and some experts contend that the products are not effective in that age group. Johnson & Johnson, Wyeth and Novartis are among the companies voluntarily pulling their cough and cold products from the market for reevaluation and potentially relabeling. The FDA may consider a ban on this class of product in children up to 6 years old.

Reuters. Drugmakers recall infant cough and cold medicine. *USA Today*. 2007 Oct 11.
http://www.usatoday.com/news/health/2007-10-11-cough-cold-recall_N.htm

The "Wal-Mart Effect" … is how it is being described. You can't buy advertising like this! When Wal-Mart took the initiative last year to provide a list of generic drugs at $4.00 each it stimulated other giant retailers to do likewise. Target and K-Mart soon followed with their own plans and Publix is now offering some generic antibiotics free. The overall effect has been a slowing in the rise of drug prices which is good news, although this will likely not have a dramatic effect as prices will continue to rise due to very expensive new drugs and aging Boomers. A side benefit from this "price war," has been an increased awareness and acceptance of generic medications to the general consuming public.

Saul S. Helped by generics, inflation of drug costs slows. *New York Times*. 2007 Sep 21.
http://www.nytimes.com/2007/09/21/business/21generic.html?_r=1&ref=health&oref=slogin

3rd class of drugs? … The FDA will hold a public meeting on November 14 to gain information and feedback about creating a "3rd class of drugs" that would be available over-the-counter but, only with pharmacist consultation. There are a few drugs now available in such a category, eg, Plan B emergency contraceptive and pseudoephedrine products. If this "3rd class" comes about, the pharmacist would have an opportunity to expand use of their cognitive skills. *–submitted by Dr. R. Lee Evans*

FDA explores behind-the-counter drug sales. Reuters. 2007 Oct 3.
http://today.reuters.com/news/articlenews.aspx?type=healthNews&storyid=2007-10-03T142801Z_01_N03213420_RTRUKOC_0_US-FDA-PRESCRIPTIONS.xml

AUBURN HSOP FACULTY and STUDENTS in the literature …

- Smoot LC. Anemia: Focus on common types and treatment. *Drug Topics*. 2007;151(14):58-67.
- Smoot LC, Boothby LA, Gillett RC. Clinical Assessment and Treatment of ADHD in Children. *Int J Clin Pract*. 2007;61(10):1730-8.
- Lloyd KB, Berger BA. Communication issues concerning sensitive issues: Fibromyalgia. *US Pharm*. 2007 Sep;32(9):61, 62, 65.
- Whitley HP, Moorman KL. Interference with smoking-cessation effects of varenicline after administration of immediate-release amphetamine-dextroamphetamine. *Pharmacotherapy*. 2007 Oct;27(10):1440-1445.

NEW RESOURCES in the DILRC …

- Chisholm-Burns MA, Wells BG, Schwinghammer T, Malone PM, Kolesar JM, Rotschafer JC, DiPiro JT, eds. *Pharmacotherapy: Principles & Practice*. NY: McGraw-Hill, 2008.
- Abood RR. *Pharmacy Practice and the Law*. 5th ed. Sudbury, MA: Jones and Bartlett, 2008.

TIMELY TOP TECH TIP …

HealthVault … A new Microsoft initiative, *HealthVault* is a web site that will allow consumers to create an account in which to store their health information. Consumers can then give access to the site/account to their physicians, hospitals, and other health professionals who can both access the stored information and add new information such as electrocardiograms and laboratory data. A number of organizations are "signed up" such as the American Heart Association, Johnson & Johnson, and Mayo clinic. It's no surprise that privacy is a primary concern. It will take years for such a concept to take hold, but it likely will; for instance, look at online banking …

Lohr S. Microsoft offers system to track health records. *New York Times*. 2007 Oct 5.
http://www.nytimes.com/2007/10/05/technology/05soft.html?_r=1&ref=health&oref=slogin

The last "dose" …

"No wise man ever wished to be younger."
--Jonathan Swift (1667-1745), Irish satirist, journalist and author

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