AU InforMed

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Key Inforbits

- Significant reports from the FDA
- Pet toxicology
- Direct-to-consumer ad pulled
- Vocabulary word – limerance
- Topical medications are not innocuous
- Words vs. actions

NEW DRUGS, and other related stuff …

New Drug … (2/21/2008) The FDA has licensed a treatment for hemophilia A, a rare, hereditary blood-clotting disorder that affects approximately 15,000 individuals, almost exclusively males, in the US. The new treatment is **Xyntha Antihemophilic Factor (Recombinant) Plasma/Albumin Free**, by Wyeth Pharmaceuticals. It is a genetically engineered version of factor VIII, a protein essential for the clotting of blood. Xyntha is licensed for the control and prevention of bleeding, which can occur spontaneously or after an accident or injury in patients with hemophilia A, and to help prevent surgical bleeding in these patients. The most frequently reported adverse reaction was headache. When used to prevent bleeding in surgery, the most frequently reported adverse reaction was fever. Most adverse reactions reported in either study were considered mild or moderate in severity.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01799.html

New Combination … (2/15/2008) Abbott has received FDA **approval for SIMCOR®**, the first fixed-dose combination of two widely prescribed cholesterol therapies, Niaspan® (Abbott's proprietary niacin extended-release) and simvastatin. SIMCOR® is approved for use along with diet to lower levels of elevated total cholesterol, LDL "bad" cholesterol and triglycerides, and to raise HDL "good" cholesterol in patients with complex lipid disease when treatment with simvastatin or Niaspan monotherapies are not considered adequate.
http://www.abbott.com/global/url/pressRelease/en_US/60.5:5/Press_Release_0577.htm

New Generic … (2/6/2008) The FDA has approved the first generic versions of Fosamax (**alendronate sodium tablets**), used to treat osteoporosis. Teva Pharmaceuticals USA was approved to manufacture alendronate sodium tablets in three once-daily dosing strengths (5 mg, 10 mg, and 40 mg) and two once-weekly dosing strengths (35 mg and 70 mg). Barr Laboratories was approved to manufacture a 70 mg once-weekly dose of the drug. The labeling of the generic alendronate sodium tablets may differ from that of Fosamax because some portions of the labeling are protected by patents and exclusivity.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01793.html [FDA News]

MedWatch … (2/7/2008) The FDA announced its intention to take **enforcement action against companies marketing unapproved, injectable colchicine**, a drug used to treat gout. Colchicine is a highly toxic drug that can easily be administered in excessive doses, especially when given intravenously. The FDA is aware of 50 reports of adverse events associated with the use of

intravenous colchicine, including 23 deaths. Potentially fatal effects include low blood cell counts, cardiac events, and organ failure. This action does not affect colchicine tablet products. After these dates, all injectable colchicine products must have FDA approval to be manufactured or shipped interstate.
Read the complete 2008 MedWatch Safety Summary, including a link to the FDA News Release regarding this issue at: http://www.fda.gov/medwatch/safety/2008/safety08.htm#colchicine

MedWatch … (2/8/2008) The FDA issued an early communication about an **ongoing safety review regarding Botox and Botox Cosmetic.** The FDA has received reports of systemic adverse reactions including respiratory compromise and death following the use of botulinum toxins types A and B for both FDA-approved and unapproved uses. The reactions reported are suggestive of botulism. The most serious cases included hospitalization and death, and occurred mostly in children treated for cerebral palsy-associated limb spasticity; this is not an approved use in the U.S. See the FDA's "Early Communication about an Ongoing Safety Review" for Agency recommendations and additional information for healthcare professionals.
Read the complete 2008 MedWatch Safety Summary including a link to the FDA's Early Communication about an Ongoing Safety Review regarding this issue at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#botox

MedWatch … (2/8/2008) Chattem, Inc. and the FDA announced a voluntary nationwide **recall of its Icy Hot Heat Therapy products**, including consumer "samples" that were included on a limited promotional basis of its 3 oz Aspercreme product. The products were recalled because of consumer reports of first, second and third degree burns as well as skin irritation. All lots and sizes of the following Icy Hot Heat Therapy products were recalled:

Icy Hot Heat Therapy Air Activated Heat - Back
Icy Hot Heat Therapy Air Activated Heat - Arm, Neck, and Leg
Icy Hot Heat Therapy Air Activated Heal - Arm, Neck, and Leg single consumer use "samples" in cartons of 3 oz. Aspercreme Pain Relieving Cream.

Consumers should stop using the products, discard them, or return them to the manufacturer.
Read the complete 2008 MedWatch Safety Summary including a link to the manufacturer's press release regarding this issue at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Chattem

MedWatch … (2/11/2008) The FDA informed healthcare professionals of important warnings and instructions for **Heparin Sodium Injection** use. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension. Most events developed within minutes of heparin initiation although the possibility for a delayed response has not been excluded. The reports have largely involved use of multiple-dose vials. Serious adverse events have recently been reported in patients who received higher bolus doses (5000-50,000 units). The manufacture of multiple-dose vials of heparin sodium has been suspended pending the completion of an ongoing investigation. Because heparin sodium is a medically necessary product and serious public health consequences would result if there were a sudden shortage of the drug, the multiple-dose vials of heparin sodium manufactured by Baxter that are currently in distribution will not be recalled.
Read the complete 2008 MedWatch Safety Summary including a link to the FDA Public Health Advisory, Q & A Document, and News Release regarding this issue at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#HeparinInj2

Reviews of Note …

- Zerilli T, Pyon EY. Sitagliptin phosphate: A DPP-4 inhibitor for the treatment of type 2 diabetes mellitus. *Clin Ther*. 2007 Dec;29(12):2614-2634.
- Cheshire WP Jr, Fealey RD. Drug-induced hyperhidrosis and hypohidrosis: Incidence, prevention and management. *Drug Safety*. 2008;31(2):109-126.
- Li J, Tripathi RC, Tripathi BJ. Drug-induced ocular disorders. *Drug Safety*. 2008; 31(2):127-141.
- Loder E, Rizzoli P. Tension-type headache. *BMJ*. 2008 Jan 12;336:88-92.
- Raz I, Chairperson. 1st World Congress on Controversies in Diabetes, Obesity and Hypertension (CODHy), October 26-29, 2006. *Diabetes Care*. 2008 Feb;31(Suppl 2):S111-S316. (34 articles)
- MacLean C, Newberry S, Maglione M, McMahon M, Ranganath V, Suttorp M, et al. Systematic review: Comparative effectiveness of treatments to prevent fractures in men and women with low bone density or osteoporosis. *Ann Intern Med*. 2008 Feb 5;148(3):197-213.

FROM THE LAY LITERATURE about medicine …

Pet toxicology … This web site tells the story of a dog who became severely ill from eating raisins. This is an apparently little known problem that too many grapes or raisins may cause renal failure in dogs. In addition to this information, there are two other links (at the bottom of the page) that give more general information on common foods (eg, chocolate) and household chemicals (eg, antifreeze) that can be deadly to pets. There is also an animal poison control center available 24/7 (be careful, as there may be a charge). Who knew …?

http://www.snopes.com/critters/crusader/raisins.asp *Submitted by Dr. M.T. Reed*

Safe again … Once again, the power and might of the United States Congress has been brought to bear against the scourge of bad advertising. An advertisement by Pfizer for Lipitor® running since 2006 featured Dr. Robert Jarvik, inventor of an artificial heart. Several have called into question the appropriateness of using Dr. Jarvik to promote a drug to the general public (he is neither a licensed physician or cardiologist) and using a stunt double in "rowing scenes" implying Dr. Jarvik is an avid rower, which he apparently is not. Based at least partly on a U.S. House Committee on Energy and Commerce inquiry launched in January, Pfizer has chosen to withdraw the ad. Your tax dollars at work …

Saul S. Drug ads raise questions for heart pioneer. *New York Times*. 2008 Feb 7. http://www.nytimes.com/2008/02/07/business/media/07jarvik.html?_r=1&th&emc=th&oref=slogin

Johnson A. Pfizer will pull some Lipitor ads in wake of probe. *Wall Street Journal*. 2008 Feb 26; p. B5.

Vocabulary … **limerance** … first stage of attraction where there is bliss and euphoria and the newness of love. Sounds good, right? Well, if it goes too far, too long, it becomes a diagnosis. Debate in psychology circles likens it to obsessive-compulsive behavior or addiction. Most of the time, such feelings subside in intensity, but for a few it keeps on giving. It may appear in the American Psychiatric Association's handbook of mental disorders in 2012. Stay tuned …

Jayson S. 'Limerance' makes the heart grow far too fonder. *USA Today*. 2008 Feb 7. http://www.usatoday.com/news/health/2008-02-06-limerence_N.htm

Pharmacist Errors … A big page one story from *USA Today* on drug errors at your local pharmacy. Walgreen's and CVS were commonly mentioned and used for examples. The thrust of the article was largely tying pharmacist workload to error rates. Several severe examples (deaths and disabilities) of drug errors were cited. The chain stores were accused of focusing on volume of prescriptions at the expense of safety; implications were that pharmacists are 'incentivized' to fill as many prescriptions as possible by tying productivity/pay to it in some fashion. Discussion also centered on what is a reasonable workload (eg, number of prescriptions per day per pharmacist). There is no standard, but 150 prescriptions per pharmacist per day is used in North Carolina as a guideline. A 'must read' for pharmacists.

McCoy K, Brady E. Rx for errors: speed, high volume can trigger mistakes. *USA Today*. 2008 Feb 12. http://www.usatoday.com/money/industries/health/2008-02-11-prescription-errors_N.htm

Topical dangers … A 'review' article on some of the hazards of topical medications that are over-the-counter. There are many such medications and just because they are over-the-counter and topical doesn't make them innocuous. The now classic case of the high school athlete who overdosed with topical methylsalicylate and died is used as the prime example. Some of the ingredients of the 14 that are listed in addition to methylsalicylate are some local anesthetics, hydrocortisone, hydroquinone (skin lightener), and topical antibiotics. It's a worthwhile read, to keep you up on what your patients are using.

Goldman L. Go easy on medicated lotions, creams, gels. *CNN.com*. 2008 Feb 5. http://www.cnn.com/2008/HEALTH/02/05/healthmag.creams/index.html

AUBURN HSOP FACULTY and STUDENTS in the literature …

- Felkey BG, Fox BI. To iPhone or not, that is the question. *Hosp Pharm*. 2008 Feb;43(2):140, 142, 154.
- Evans RL. Auburn University Harrison School of Pharmacy: Educational developments are underway. *Alabama Pharmacy*. 2007 4th Quart, p. 15.

NEW RESOURCES in the DILRC …

- *Drug Facts and Comparisons 2008*. Bound edition. St. Louis: Facts and Comparisons/Wolters Kluwer Health, 2008.
- Tatro DS, ed. *Drug Interaction Facts 2008*. Bound edition. St. Louis: Facts and Comparisons/Wolters Kluwer Health, 2008.
- McEvoy G, ed. *AHFS Drug Information 2008*. Bethesda, MD: American Society of Health-System Pharmacists, 2008.

The last "dose" …

"I have always thought the actions of men the best interpreters of their thoughts."
--John Locke, English Philosopher (1632 – 1704)

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