AU InforMed

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Key Inforbits

- 4 new drugs approved in the last few weeks
- Some drug labeling changes/reminders
- New guidelines for pulmonary embolism
- "Dispense as written" has other costs
- Poison control centers on the budget block
- What is a poison?

NEW DRUGS, and other related stuff …

New Drug … (2/25/2001) The FDA has approved **azilsartan medoxomil (Edarbi™ tablets** by Takeda Pharmaceutical North America of Deerfield, Ill.) to treat hypertension in adults. It is an angiotensin II receptor blocker (ARB). Clinical studies showed Edarbi™ more effective in lowering 24-hour blood pressure compared with two other ARBs, Diovan® (valsartan) and Benicar® (olmesartan). Edarbi™ will be available in 80 mg and 40 mg tablets, with the recommendation of 80 mg once daily. The 40 mg dose is for patients who are also treated with high-dose diuretics. Edarbi™ has a boxed warning stating that the drug should be avoided in pregnant women because use of the drug during the second or third trimester can cause injury and even death in the developing fetus.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm244722.htm (FDA press release)
http://www.edarbi.com/default.aspx (Edarbi™ package insert)

New Drug … (3/1/2011) The FDA has approved **roflumilast (Daliresp™** tablets by Forest/Nycomed), to decrease the frequency of exacerbations or worsening of symptoms from severe chronic obstructive pulmonary disease (COPD). Roflumilast, a new drug class for the treatment of COPD, inhibits the enzyme phosphodiesterase type 4 (PDE-4). It is indicated for people with severe COPD to treat the symptoms of cough and excess mucus linked to bronchitis. Roflumilast is not intended to treat another form of COPD which involves primary emphysema. Roflumilast should not be used to treat acute bronchospam, and is not recommended for people younger than 18 years. The most common side effects reported include diarrhea, nausea, headache, insomnia, back pain, decreased appetite, and dizziness.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm244989.htm

New Drug … (3/9/2011) The FDA has approved **belimumab (Benlysta®** by Human Genome Sciences Inc. and will co-market in the U.S. with GlaxoSmithKline) to treat patients with active, autoantibody-positive lupus (systemic lupus erythematosus - SLE) who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs. Benlysta® is given by intravenous infusion and is the first inhibitor to target B-lymphocyte stimulator (BLyS) protein, which may reduce the number of abnormal B cells thought to be a problem in lupus. The most common drug side effects include nausea, diarrhea, and fever. Patients also commonly experienced infusion reactions, so consider pre-treatment with an antihistamine. Prior to Benlysta®, the FDA last approved drugs to treat lupus were Plaquenil (hydroxychloroquine) and corticosteroids, in 1955. Aspirin was approved to treat lupus in 1948.

Lupus is a serious, potentially fatal, autoimmune disease that attacks healthy tissues. It disproportionately affects women, and usually develops between ages 15 and 44. The disease affects many parts of the body including the joints, the skin, kidneys, lungs, heart, and the brain. When common lupus symptoms appear they can present as swelling in the joints or joint pain, light sensitivity, fever, chest pain, hair loss, and fatigue. In the U.S., sufferer's range from 300,000 to 1.5 million people. People of all races can be afflicted, but African American women have a 3 times higher incidence than Caucasian women.

FDA approves Benlysta to treat lupus: First new lupus drug approved in 56 years. FDA News Release. 2011 Mar 9. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm246489.htm

New Drug … (3/25/2011) The FDA has approved **ipilimumab (Yervoy™** by Bristol-Myers Squibb) to treat patients with late-stage (metastatic) melanoma, the most dangerous type of skin cancer. Ipilimumab is a monoclonal antibody that blocks cytotoxic T-lymphocyte antigen or CTLA-4 which may play a role in slowing down or turning off the body's immune system, affecting its ability to fight off cancerous cells. Ipilimumab may work by allowing the body's immune system to recognize, target, and attack cells in melanoma tumors. The drug is given intravenously. Safety and effectiveness were established in a single international study of 676 patients with melanoma. All patients in the study had stopped responding to other commonly used treatments for melanoma and the disease had spread or could not be surgically removed. Patients who received ipilimumab lived an average of about 10 months. Common side effects included fatigue, diarrhea, skin rash, endocrine deficiencies (gland or hormone), and inflammation of the intestines (colitis). Severe to fatal autoimmune reactions were seen in 12.9% of patients treated with ipilimumab.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm1193237.htm

New Labeling … (2/22/2011) **Antipsychotic drugs: Class Labeling Change** - Treatment During Pregnancy and Potential Risk to Newborns including Haldol®, FazaClo®, Fanapt®, Clozaril®, Risperdal®, Zyprexa®, Seroquel®, Abilify®, Geodon®, Invega®, Loxitane®, Moban®, Navane®, Orap®, Saphris®, Stelazine®, Thorazine®, Symbyax®.
The new drug labels now contain more and consistent information about the potential risk for abnormal muscle movements (extrapyramidal signs or EPS) and withdrawal symptoms in newborns whose mothers were treated with these drugs during the third trimester of pregnancy. Healthcare professionals should be aware of the effects of antipsychotic medications on newborns when the medications are used during pregnancy. Patients should not stop taking these medications if they become pregnant without talking to their healthcare professional, as abruptly stopping antipsychotic medications can complicate treatment. FDA Safety Alert. 2011 Feb 22.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm244175.htm

New Drug Labeling Reminder … (3/30/2011) The FDA has issued an alert about the important storage and handling requirements for **Pradaxa® (dabigatran etexilate mesylate)** capsules. Due to the potential for product breakdown from moisture and loss of potency, Pradaxa® capsules should only be dispensed and stored in the original bottle or blister package that contain a dessicant. Pradaxa® capsules should not be repackaged. The Pradaxa® label states that once opened, the product must be used within 30 days.

FDA News: Safety. Pradaxa (dabigatran etexilate mesylate) Capsules: Special Storage and Handling Requirements. FDA News. 2011 Mar 30.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm

FROM THE MEDICAL LITERATURE …

Guidelines for management of massive and submassive pulmonary embolism and iliofemoral deep vein thrombosis and chronic thromboembolic pulmonary hypertension, have been issued by the American Heart Association.

Jaff MR, McMurtry MS, Archer SL, Cushman M, Goldenberg NA, Goldhaber SZ, Jenkins JS, Kline JA, Michaels AD, Thistlethwaite P, Vedantham S, White RJ, Zierler BK; on behalf of the American Heart Association Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation, Council on Peripheral Vascular Disease, and Council on Arteriosclerosis, Thrombosis and Vascular Biology. Management of massive and submassive pulmonary embolism, iliofemoral deep vein thrombosis, and chronic thromboembolic pulmonary hypertension: a scientific statement from the American Heart Association. *Circulation.* 2011;123:●●●–●●●. [ahead of print]
http://circ.ahajournals.org/cgi/reprint/CIR.0b013e318214914fv1

"Dispense as written" has other costs … A recent study looked at over 5 million prescriptions from a large pharmacy benefit manager (PBM) and separated the "dispense as written" (DAW) prescriptions in two categories, physician-ordered (2.7%) and patient-requested (2%). They found that the DAW prescriptions were 1.5 and 1.6 times less likely to be filled by the patient. The non-filled prescriptions were more likely to be for chronic medications. Older physician specialists in the northeast and older patients (>55 years) were more likely to prescribe/request DAW. The most common drugs were those with a narrow therapeutic index (eg, thyroid hormones, warfarin). Reversing some of these DAWs could result in substantial savings and encourage more patient compliance with therapy.

Shrank WH, Liberman JN, Fischer MA, Avorn J, Kilabuk E, Chang A, Kesselheim AS, Brennan TA, Choudhry NK. The consequences of requesting "Dispense as written". Am J Med. 2011 Apr;124(4):309-317.

Reviews of Note …

- Gray CL, Walters-Smith NE. Febuxostat for treatment of chronic gout. Am J Health-Syst Pharm. 2011 Mar 1;68:389-398.
- Bergman M, ed. Prediabetes and diabetes prevention. Med Clin N Am. 2011 Mar;95(2):289-425. [10 articles]
- Munier CML, Andersen CR, Kelleher AD. HIV vaccines: Progress to date. Drugs. 2011;71(4):387-414.
- Lyseng-Williams KA. Levetiracetam: A review of its use in epilepsy. Drugs. 2011;71(4):489-514.
- Wang L, Mcleod HL, Weinshilboum RM. Genomics and drug response. N Engl J Med. 2011 Mar 24;364(12):1144-1153.
- Campen CJ, Dragovich T, Baker AE. Management strategies in pancreatic cancer. Am J Health-Syst Pharm. 2011 Apr 1;68:573-584.
- Baysari MT, Westbrook J, Braithwaite J, Day RO. The role of computerized decision support in reducing errors in selecting medicines for prescription: Narrative review. Drug Saf. 2011;34(4):289-298.
- Pelchovitz DJ, Goldberger JJ. Caffeine and cardiac arrhythmias: A review of the evidence. Am J Med. 2011 Apr;124(4):284-289.
- Smith HS, Argoff CE. Pharmacological treatment of diabetic neuropathic pain. Drugs. 2011;71(5):557-589.
- Garnock-Jones KP, Giuliano AR. Quadrivalent human papillomavirus (HPV) types 6, 11, 16, 18 vaccine: For the prevention of genital warts in males. Drugs. 2011;71(5):591-602.

From the Lay Literature …

Poison Centers on the block … All in the name of budget cuts, Congress is considering cutting nearly all federal funding for poison control centers. This would effectively gut the nationwide network of 57 poison control centers. The proposal would cut $27.3 million (93% of funding) from a program that has demonstrated in numerous studies a return on investment of at least $7 for every dollar spent. In addition, it is proposed to establish a single, national call center for the 12,000+ daily calls; efficient? Possible?? And all of this in the traditional week where attention is shown on poison control efforts!

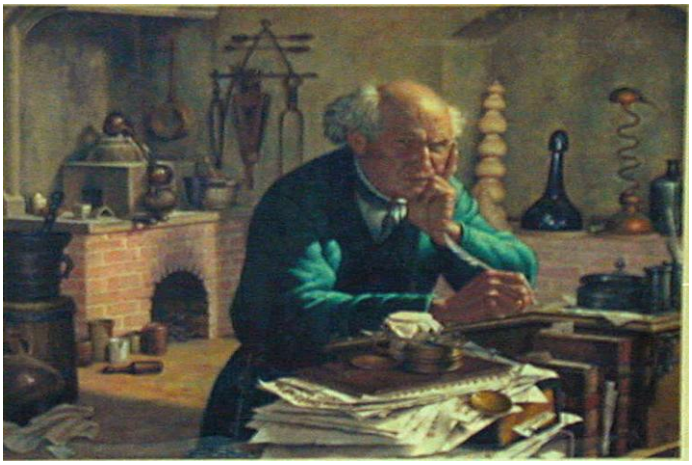
Hudson W. In poison emergencies, who'll answer your call? CNN.com 2011 Mar 22.
http://www.cnn.com/2011/HEALTH/03/22/poison.control.risk.closure/index.html?iref=allsearch

NEW RESOURCES in the DIC …

- Who's Who in Managed Care Pharmacy, 2010-2011. Alexandria, VA: Academy of Managed Care Pharmacy, 2010.
- Chisholm-Burns MA, Schwinghammer TL, Wells BG, Malone PM, Kolesar JM, DiPiro JT, eds. Pharmacotherapy: Principles & Practice. 2nd ed. NY: McGraw-Hill, ©2010.
- Katz MD, Matthias KR, Chisholm-Burns MA, eds. Pharmacotherapy Principles and Practice Study Guide: A Case-based Care Plan Approach. NY: McGraw-Hill, ©2011.

The last "dose" …

"All drugs are poisons the benefit depends on the dosage."
Philippus Theophrastrus Bombast
That of Aureolus Paracelsus (1493-1541)



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