Key Inforbits

- 4 new drugs approved in the last few weeks
- "Dispense as written" has other costs
- On some drug labeling changes/reminders
- Poison control centers on the budget block
- New guidelines for pulmonary embolism
- 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 bronchospasm, 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.


**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®, Symbax®. 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.


**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.


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.


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.


Reviews of Note …

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.

NEW RESOURCES in the DIC …


The last “dose” …

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