Key Inforbits

- New indication, combo and MedWatch
- Counterfeit drugs report from the FDA
- New infection control regs from the WHO
- Share, restock, reuse, donate???
- AU Pharmacy services on line!
- Happy birthday #200!!

NEW DRUGS, and other related stuff …

New Indication … Peginterferon Alfa-2a (Pegasys® by Roche) was approved for the treatment of chronic hepatitis B on May 16, 2005. It is the first and only pegylated interferon to be approved for the treatment of chronic hepatitis B in the US.


New Combo … The FDA granted approval status on May 16, 2005 for the combination tablet Trizivir® (abacavir sulfate, lamivudine, and zidovudine by GlaxoSmithKline) for the treatment of HIV infection. Trizivir® is a fixed-dose-combination tablet that contains three nucleoside reverse transcriptase inhibitors.


MedWatch … The FDA notified healthcare professionals of an update and revision to a 1998 notice with advice regarding the safety of albumin administration in critically ill patients. This follows FDA's review of recent studies on the safety of albumin, and is consistent with recommendations made on March 17, 2005 by members of the Blood Products Advisory Committee (BPAC).

Read the complete MedWatch 2005 Safety summary, including a link to FDA/CBER notice at:

http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#albumin

MedWatch … Scios and FDA notified healthcare professionals of revisions to the ADVERSE REACTIONS/Effect on Mortality section of the prescribing information for Natrecor® [nesiritide], indicated for acutely decompensated congestive heart failure. The Dear Healthcare Professional letter also provides information from Scios on several published reports that raise the question of whether the product may have adverse effects on survival and kidney function compared to controls (generally nitroglycerin and diuretics).

Read the complete MedWatch 2005 Safety summary, including links to the Dear Healthcare Professional letter and revised label, at:

http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#natrecor
MedWatch … The FDA issued a Talk Paper to notify the public about the abuse of dextromethorphan (DXM), an ingredient found in many over-the-counter (OTC) cough and cold remedies. The agency is working with other health and law enforcement authorities to address this serious issue and warn the public of potential harm, after five recently reported deaths of teenagers that may be associated with the consumption of powdered DXM sold in capsules.
http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Dextromethorphan

FROM THE MEDICAL LITERATURE …

Counterfeit Drugs Report … The FDA has released an update to its 2004 report on counterfeit drugs and they report significant progress. The number of cases investigated by the FDA nearly doubled from 2003. For a summary and links to the full report, go to the following web site.
FDA. FDA continues combating counterfeit drugs annual update reports on progress. FDA News 2005 May 18; P05-24.
http://www.fda.gov/bbs/topics/NEWS/2005/NEW01179.html

Trials registration and publishing requirements … the International Committee of Medical Journal Editors (ICMJE) have published a joint editorial stating that the member journals will not publish research from a trial that has not been properly registered, prior to the beginning of the study. There are several exceptions and caveats. Journals that are members of his organization include the New England Journal of Medicine, Journal of the American Medical Association, Annals of Internal Medicine, Lancet, Canadian Medical Association Journal and several other international journals. The editorial is available free, as an early release from the web site.
www.nejm.org

Caffeine takes another hit … An abstract from the American Psychiatric Association reported that 20 1st grade students exhibited significantly more restlessness, hyperactivity and lack of attentiveness when allowed caffeinated cola compared to noncaffeinated. This was assessed by their teacher who was blinded to drinks consumed. They had to study this?
http://www.medpagetoday.com/tbindex.cfm?tbid=1091&topicid=43

WHO adopts new international health regulations … the original guidelines were adopted in 1969 and aimed at only six diseases, cholera, plague, yellow fever, smallpox, relapsing fever and typhus. A lot has happened since then, most recently SARS and the potential epidemic of avian flu. These regulations are primarily aimed at identifying and controlling disease outbreaks more effectively. For the 60-page report, go to the site below.
WHO. Third report of Committee A. World Health Organization:58th World Health Assembly. A58/55, Agenda item 13.1. 2005 May 23,

Reviews of Note …


FROM THE LAY LITERATURE about medicine …

Share, recycle, reuse?!? … A couple of newspaper articles highlight two issues near and dear to pharmacists. One concerns recycling or reusing medicine, that many state laws do not permit. However, estimates of money saved by various such programs range from $1 to $6 billion. Several less obvious issues are also covered such as the paperwork involved, particularly when the original prescription is covered by insurance. Then there is donating to a worthy cause. The other issue is that of sharing prescriptions. It’s not just a matter of giving your neighbor your left over antibiotics for what appears to be a similar infection. Many share between spouses, just to save money, but clearly endanger the health of both.


TIMELY TOP TECH TIP …

AU PHARMACY OFFERS ONLINE REFILL SERVICE

AU Pharmacy is now offering an online refill service for faculty and staff called RxExpress. The service will be offered to students beginning this fall. If the patient requests a refill via RxExpress by noon, it will be ready the same day after 1 p.m. Requests made after noon will be ready the following business day. Faculty and staff are welcome to have their medications delivered for free and can also choose this option when they refill through the RxExpress. Check it out at [www.pharmacy.auburn.edu/aushp](http://www.pharmacy.auburn.edu/aushp)
to Morphine. May 21, 2005 marked a celebration of the 200th anniversary of the discovery of morphine, by Freidrich Wilhelm Adam Serturner (1783-1841) of Germany. A 21-year-old pharmacist’s assistant, he isolated morphine from the resinous gum of the opium poppy (Papaver somniferum). After experimenting, mostly on himself, he named the compound morphine after the Greek god of dreams, Morpheus. It was the first isolation of a natural plant alkaloid.