

AU InforMed

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Key Inforbits

- Many MedWatches
- World disease burden estimated
- Pharmacy care has an impact!
- 1918 Flu epidemic has some lessons
- Dumpster-diving has its rewards
- National Drugged and Drunk Driving Prevention Month

NEW DRUGS, and other related stuff ...

Experimental Drugs Rules Overhaul ... The FDA proposed significant regulatory changes on December 11, 2006, to **make experimental drugs more widely and easily available**. This also includes costs for which the manufacturer may be able to charge for the drug. The proposed rules are open for comments for 90 days; more detail is provided at: (http://www.fda.gov/cder/regulatory/applications/IND_PR.htm)

Also, a summary of proposed rules and several relevant web sites are provided with the *FDA News* document provided by the FDA.

FDA proposes rules overhaul to expand availability of experimental drugs. *FDA News*. 2006 Dec 11; P06-194. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01520.html>

MedWatch ... The FDA notified healthcare professionals of reports of **death and life-threatening adverse events** such as respiratory depression and cardiac arrhythmias in patients receiving **methadone**. These adverse events are the possible result of unintentional methadone overdoses, drug interactions, and methadone's cardiac toxicities (QT prolongation and Torsades de Pointes). The reports underscore the importance of knowing methadone's toxicities and unique pharmacologic properties, including dosing and monitoring recommendations. Read the complete MedWatch 2006 Safety summary, including links to the FDA Healthcare Professional Sheet, Patient Information Sheet, and new prescribing information for Dolophine regarding this issue at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Methadone>

MedWatch ... The FDA and Advanced Medical Optics, Inc. informed healthcare professionals and consumers of a **nationwide recall of 18 lots of Complete[®] MoisturePLUS multipurpose contact lens care solution and Active Packs** distributed in the United States. Certain lots were found to have bacterial contamination which compromised sterility. Non-sterility of a contact lens solution may have serious health consequences, including eye infection and microbial keratitis. Contact lens users who have the recalled product should discontinue use immediately and individuals who experience symptoms of an eye infection such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge or swelling, should remove their lenses and consult their eye care provider immediately. Read the complete MedWatch 2006 Safety summary, including links to the Manufacturer's Press Release that includes the 18 lot numbers that were recalled at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#complete>

MedWatch ... The FDA and Baxter announced revisions to the WARNINGS section of the prescribing information for Heparin to inform clinicians of the possibility of **delayed onset of heparin-induced thrombocytopenia (HIT)**, a serious antibody-mediated reaction resulting from irreversible aggregation of platelets. HIT may progress to the development of venous and arterial thromboses, a condition referred to as heparin-induced thrombocytopenia and thrombosis (HITT). Thrombotic events may be the initial presentation for HITT which can occur up to several weeks after the discontinuation of heparin therapy. Patients presenting with thrombocytopenia or thrombosis after stopping heparin should be evaluated for HIT and HITT. Read the complete MedWatch Safety summary, including links to prescribing information for heparin regarding this issue at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Heparin>

MedWatch ... The FDA announced the serious **public health risks related to compounded topical anesthetic creams**. FDA issued warning letters to five firms to stop compounding and distributing standardized versions of topical anesthetic creams, marketed for general distribution. Exposure to high concentrations of local anesthetics, like those in compounded topical anesthetic creams, can cause grave reactions including seizures, irregular heartbeats and death. Compounded topical anesthetic creams are often used to lessen pain in procedures such as laser hair removal, tattoos, and skin treatments. They may be dispensed by clinics and spas that provide these procedures, or by pharmacies and doctors' offices.

Read the complete 2006 MedWatch safety summary, including links to the FDA press release at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#compound>

MedWatch ... The FDA announced that the Agency ordered firms to **stop marketing unapproved drug products containing quinine**, citing serious safety concerns, including deaths associated with quinine products. There are multiple unapproved products containing quinine currently on the market, used off-label to treat leg cramps and similar conditions. Since 1969, FDA received 665 reports of adverse events with serious outcomes associated with quinine use, including 93 deaths. Quinine drugs are associated with serious side effects, such as cardiac arrhythmias, thrombocytopenia, and severe hypersensitivity reactions. Quaaluan, manufactured by Mutual Pharmaceutical Company, is the only quinine product approved by the FDA. Read the complete MedWatch Safety summary, including the link to the FDA press release regarding this issue at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Quinine>

FROM THE MEDICAL LITERATURE ...

AIDS may rise to No. 3 in global mortality list ... In a study that seeks to update global mortality and disease burden projections from 1996, the authors have recalculated using more current data and looking at a baseline, pessimistic and optimistic viewpoint. A big change from previous estimates is the rise and persistence of AIDS. All estimates are of course, based on huge estimates. A switch is seen in age groups from the very young to older age groups; also, one scenario has the top three killers in 2030 as HIV/AIDS, unipolar depressive disorders and ischemic heart disease. There is much more data in this 20-page article.

Mathers C, Loncar D. Projections of global mortality and burden of disease from 2002 to 2030. *PLoS Med.* 2006 Nov;3(11):e442. doi:10.1371/journal.pmed.0030442.

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030442>

Pharmacy Care ... Good ... In yet another well documented study, pharmacist counseling of 200 elderly patients in a military facility, with hypertension and hypercholesterolemia demonstrated improved medication compliance (61% to 97%) with associated improved outcomes on blood pressure and LDL-cholesterol. A wrinkle of the study was that medications were also individually packaged in time-specific packs, so it is unknown how much either variable affected the actual outcomes (pharmacists or the blister packs). Given the recognition factor of the journal (*JAMA*), it can't hurt. There is also an accompanying editorial pointing out some other areas of concern.



Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: randomized controlled trial. *JAMA*. 2006 Dec 6;296(21):2563-71.
Simpson RJ Jr. Challenges for improving medication adherence. *JAMA*. 2006 Dec 6;296(21):2614-6.

Reviews of Note ...

- Divvela S, Williams A, Meives C, Gozun E. Opioid analgesics: Comparison of pharmacokinetics and equianalgesic doses. *Hosp Pharm*. 2006 Nov;41(11):1130-1135.
- Brand KA. Intrathecal Administration. *Hosp Pharm*. 2006 Nov;41(11): Chart Insert.
- Eder W, Ege MJ, von Mutius E. The asthma epidemic. *N Engl J Med*. 2006 Nov 23;355(21):2226-35.

FROM THE LAY LITERATURE about medicine ...

1918 Flu epidemic has lessons ... An analysis of the 1918 Spanish Flu and American response has shown the benefit of various nondrug public health measures. It varied based on cities, but some of the measures taken almost 90 years ago included: quarantining houses, closing schools, restricting various large gatherings, closing common gathering places such as taverns and theaters, staggering hours of business operations and curfews. These and other measures were thought to reduce the number of deaths due to influenza by up to 70%. Many of these are simple, common sense measures, but would they survive in our era of political correctness??



Brown D. 1918 Flu epidemic teaching valuable lessons. *Washington Post*. 2006 Dec 13; p. A04.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/12/12/AR2006121201628.html?referrer=email>

Sometimes, it's the simple things ... Several large chain pharmacies were slightly embarrassed when some enterprising television reporter went dumpster-diving and turned up thousands of patient records (eg, prescription labels, refill lists, pill bottles). A common refrain was that policies were in place but not followed, and "training" was in order. Some have instituted more stringent handling of pharmacy refuse. Bottom line: it was judged "operator error."



Tucker E. Drug chains strengthen privacy policies after TV station searches trash. *USA Today*. 2006 Dec 1.

http://www.usatoday.com/money/industries/health/drugs/2006-12-01-drugstore-privacy_x.htm

Update ...

Developing Pharmacy Practice: A Focus on Patient Care ... This update was provided by the American Society of Health-System Pharmacists (ASHP) announcing that the World Health Organization (WHO), in collaboration with the International Pharmaceutical Federation (FIP), has published the 93-page handbook "Developing Pharmacy Practice: A Focus on Patient Care" for pharmacists, educators, and students all over the world in all health care settings. This link provides the full text of the handbook.

http://www.who.int/medicines/publications/WHO_PSM_PAR_2006.5.pdf



The last "dose" ...

National Drunk and Drugged Driving Prevention Month --- December 2006¹

December has been designated National Drunk and Drugged Driving Prevention Month (3D Month). In 2005, a total of 43,443 traffic fatalities occurred, 39% (16,885) of which were alcohol related (1). Among these alcohol-related fatalities, 86% (14,539) involved at least one driver, pedestrian, or bicyclist with a blood alcohol concentration (BAC) ≥ 0.08 g/dL, a level that is illegal in all states. Including both fatalities and persons who survived the crash, the percentage of persons with a BAC ≥ 0.08 g/dL was 32% for pedestrians, 27% for motorcycle operators, 22% for passenger-car drivers, and 21% for drivers of light trucks.



Male drivers and drivers aged 21--24 years had the highest BACs. A previous conviction for driving while impaired had been recorded for 9% of drivers with BACs ≥ 0.08 g/dL who were involved in fatal crashes, and 25% had had their licenses suspended or revoked previously. A program planner, which contains sample public-service announcements, media tool kits, and program guidance for 3D Month, is available from the National Highway Traffic Safety Administration at

<http://www.stopimpaireddriving.org>

¹National Highway Traffic Safety Administration. Traffic safety facts, 2005 data: alcohol. Washington, DC: National Highway Traffic Safety Administration; 2006. DOT HS 810 616. Available at: http://www-nrd.nhtsa.dot.gov/pdf/nrd-30/ncsa/tsf2005/2005tsf/810_616/images/alcohol.pdf.

MMWR. Dec 8;55(48):1293 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5548a1.htm>

After that sobering thought, please, have a



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

Auburn University, Harrison School of Pharmacy, Drug Information Center

• Phone 334-844-4400 • Fax 334-844-8366 • <http://www.pharmacy.auburn.edu/dilrc/dilrc.htm>

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