AU InforMed

Volume 3 Number 20 (Issue 83)

Thursday, August 4, 2005

Key Inforbits

- Counterfeit drugs from the U.K.
- Vaccination/immunization news
- It's not Big Brother, but Big Pharma
- More sleep problems ahead for boomers
- More info on mifepristone-induced infection
- Drugs and in patients who don't take them

NEW DRUGS, and other related stuff ...

MedWatch ... The FDA issued an alert about the recent recall of a batch of counterfeit "Lipitor" (atorvastatin) sold in the United Kingdom (U.K.). The counterfeit Lipitor 20mg tablets were recalled in the U.K. on July 28, 2005. Health authorities in the U.K. stated that initial results of tests do not indicate that this product poses an immediate risk to patients. Some U.S. residents may have obtained prescription drugs from the U.K. through on-line or storefront operations that do not supply legitimate, FDA-approved products, or through state-run drug importation programs that facilitate the purchase of unapproved foreign drugs. U.S. patients who have the identified U.K. drugs should stop using them and should consult their physician or pharmacist if they have any questions or concerns.

Read complete MedWatch 2005 Safety summary, including a link to the FDA news release, at: <u>http://www.fda.gov/medwatch/safety/2005/safety05.htm#fakelipitor</u>

MedWatch ... Perrigo and FDA have issued a recall of all lots of concentrated infants' drops that are packaged with a dosing syringe bearing only a "1.6 mL" mark containing: 1] acetaminophen, 2] acetaminophen, dextromethorphan HBr, and pseudoephedrine HCl, or 3] dextromethorphan HBr, and pseudoephedrine HCl. The dosing syringe may be confusing in determining the proper dose for infants under 2 years of age as directed by a doctor and could lead to improper dosing, including overdosing. The following products are being recalled:

- * Cherry Flavor Infant Pain Reliever 160 mg Acetaminophen (0.5oz. and 1.0oz)
- * Grape Flavor Infant Pain Reliever 160 mg Acetaminophen (0.5oz. and 1.0oz)
- * Cherry Flavor Cough and Cold Infant Drops (0.5oz)
- * Cherry Flavor Decongestant and Cough Infant Drops (0.5oz)

Read the complete MedWatch 2005 Safety summary, including a link to the FDA Talk Paper and the firm press release, at:

http://www.fda.gov/medwatch/safety/2005/safety05.htm#Perrigo

FROM THE MEDICAL LITERATURE ...

National Immunization Awareness Month ... Did you know that August is National Immunization Awareness Month (NIAM)? The goal of NIAM is to increase awareness about immunizations from infants to the elderly. This year's campaign is focused around the theme, "Are You Up to Date? Vaccinate!" to remind people of all ages of the importance of

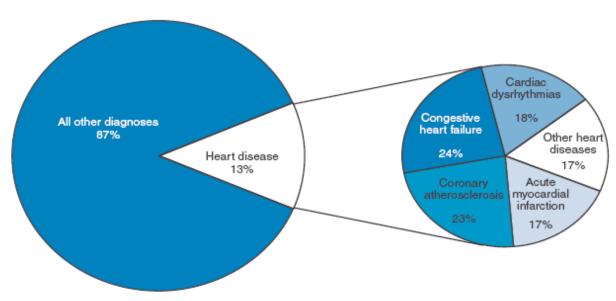
immunization. For more official information and for items such as brochures, posters, template materials, etc, go to the web site below, sponsored by the Centers for Disease Control and Prevention (CDC).

http://www.cdc.gov/nip/events/niam/

Vaccinations are up! ... The National Immunization Survey (NIS) provides vaccination coverage estimates for children aged 19 to 35 months for the 50 states and 28 selected urban areas. The latest report summarizes results from the 2004 NIS, and indicates nationwide increases in standard vaccine coverage. The levels are an important accomplishment by exceeding for the first time, the *Healthy People 2010* goal of \geq 80% coverage for the 4:3:1:3:3 vaccine series. More good news: Alabama (just slightly) exceeds the national averages. CDC. National, state, and urban area vaccination coverage among children aged 19-35 months-United States, 2004. *MMWR* 2005 Jul 29;54(29):717-21.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5429a1.htm

Heart Disease stats ...



Hospitalizations for Heart Disease, by Diagnosis* and Percentage Distribution[†] — United States, 2003

CDC. QuickStats from the National Center for Health Statistics. *MMWR* 2005 Jul 22;54(28):704. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5428a4.htm

Reviews of Note ...

- Douglas RM, Hemilä H. Vitamin C for preventing and treating the common cold. *PLoS Medicine* 2005 Jun;2(6):e168. [an update of a systematic review] http://medicine.plosjournals.org/perlserv/?request=getdocument&doi=10.1371/journal.pmed.0020168
- Hempenstall K, Nurmikko TJ, Johnson RW, A'Hern RP, Rice ASC. Analgesic therapy in postherpetic neuralgia: A quantitative systematic review. *PLoS Medicine* 2005 Jul;2(7)e164:0628-44. http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020164

- Knollmann BC, Smyth BJ, Garnett CE, Salesiotis AN, Gvozdjan DM, Berry NS, et al. Personal digital assistant-based drug reference software as tools to improve rational prescribing: Benchmark criteria and performance. *Clin Pharmacol Ther* 2005 Jul;78(1):7-18.
- Osterberg L, Blaschke T. Drug therapy: Adherence to medication. *N Engl J Med* 2005 Aug 4;353(5):487-97.

FROM THE LAY LITERATURE about medicine ...

Pharmaceutical industry influence raises blood pressure ... In a rather public split, the American Society of Hypertension and their former official journal, the *American Journal of Hypertension* have parted ways. It's a little unclear as to who took the first step, but the journal's editor (and co-founder of the Society) is upset about his view that the Society has been, and continues to be, improperly influenced by pharmaceutical industry money, mostly in sponsored CE programs. The term "irreconcilable differences" has been used to describe the split and gives an idea as to the level of acrimony in this situation. This situation even made the academic news. Winslow R, Zimmerman R. High blood pressure: Doctors sever ties with medical journal. *Wall Street Journal.com* 2005 Jul 29; p. B1.

Mangan KS. Professional group and journal sever ties, each citing concerns about potential conflicts. *Chronicle Higher Education* 2005 Aug 1.

http://chronicle.com/daily/2005/08/2005080103n.htm (subscription required)



PhRMA announces new guidelines for direct-to-consumer advertising ... In a press release on August 2, 2005, the Pharmaceutical Research and Manufacturers Association (PhRMA) announced new, voluntary guidelines to improve direct-to-consumer advertising of pharmaceutical agents. As you might imagine, not everyone is thrilled or impressed by the guidelines, which seem to include just about everyone except the pharmaceutical manufacturers. For the press release and complete guidelines, go to:

http://www.phrma.org/mediaroom/press/releases/02.08.2005.1195.cfm For an opposing viewpoint of their benefit, go to:

Saul S. Drug makers to police consumer campaigns. *New York Times.com* 2005 Aug 3. http://www.nytimes.com/2005/08/03/business/media/03adco.html?

Sleep on it ... Bad news for Boomers. If you are having trouble sleeping now, it will probably get worse; and if you're not having trouble your chances double from being twenty-something to being over age 65. There are, of course, a variety of problems, not just age, but it's no accident that at least two new sleep aids have been approved in the last few months. Elias M. Age and sleep play catch-up. *USA Today.com* 2005 Jul 27.

http://www.usatoday.com/news/health/2005-07-27-age-and-insomnia_x.htm

Price of obesity ... a different perspective on obesity, particularly for the morbidly obese; what does it cost? Impact can range from cost of food and clothes, to the projection of wages (obese typically are lower earners) and hold lower level jobs. This can run in families as well, ie, inheritance is likely to be lower, since parents may be obese and therefore lower earners, etc, etc. This is another tack to help convince your patients to keep up the effort to lose weight. Costello D. The price of obesity. *Los Angeles Times.com* 2005 Aug 1.

http://www.latimes.com/features/health/la-he-obesecost1aug01,1,2068698.story?coll=la-headlines-health

<u>Update</u> ...

Mifepristone-induced septic shock ... as a follow up to the MedWatch report of last week (*AU InforMed* 2005 Jul 25;3(19):72) concerning four deaths in women post-abortion with mifepristone, a new report is published online (print in September) that discusses the history and pathophysiology of this problem. It's not as new as you may think. Miech RP. Pathophysiology of mifepristone-induced septic shock due to *Clostridium sordellii. Ann Pharmacother* 2005 Sep;39:xxx. <u>www.theannals.com</u> (full text requires subscription) Also, an investigation report from the CDC concerning the two most recently identified U.S. deaths after medical abortion. CDC. *Clostridium sordellii* toxic shock syndrome after medical abortion with mifepristone and intravaginal misoprostol -United States and Canada, 2001-2005. *MMWR* 2005 July 29;54(29):724. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5429a3.htm

AUBURN HSOP FACULTY in the literature ...

• Wargo KA, McConnell V, Jennings M. Amoxicillin/telithromycin-induced rash in infectious mononucleosis [ltr]. *Ann Pharmacother* 2005 Sep;39:xxx.

📚 <u>The last "dose"</u> ...

Drugs don't work in patients who don't take them.

- С. Everett Коор, MD [1916-] (former И.S. Surgeon General, 1982-1989)

