

AU InforMed

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Key Inforbits

- New indication, prevent Hep B reinfection
- MedWatches: recalls, glass, misbranding
- Review of compliance studies
- Edging toward universal health care?
- Drugs in the water
- 1984

NEW DRUGS, and other related stuff ...

New Indication ... The FDA approved HepaGam B (by Cangene Corp. of Winnipeg, Canada) for the prevention of hepatitis B (HBV) reinfection in certain liver transplant patients on April 6, 2007. HepaGam B is the first product of its kind (an immune globulin product) approved for this purpose. HepaGam B works by providing an immediate immune response to the virus that protects patients previously exposed to HBV. Patients must receive injections at the time of their liver transplant and continued for life. This product is manufactured from human plasma collected at U.S. licensed plasma centers from healthy donors. In January 2006, FDA licensed HepaGam B to prevent infection with HBV for the following other purposes: after acute exposure to blood or certain body fluids containing HBV; perinatal exposure of infants to mothers previously exposed to HBV; sexual exposure to persons previously exposed to HBV; and household exposure to persons with acute HBV infection.

FDA licenses first biologic product to prevent hepatitis B reinfection in liver transplant patients. *FDA News*. 2007 Apr 6; P07-60.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01602.html>

MedWatch ... (4/6/2007) The FDA notified healthcare professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride. These products are used to treat nausea and vomiting in adults and children. The products have been marketed under various names, including Tigan, Tebamide, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA. FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their healthcare professional. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms. Read the complete MedWatch 2007 Safety summary, including a link to the FDA Press Release regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide>

MedWatch ... (4/10/2007) Ortho-McNeil and the FDA informed healthcare professionals and consumers of a nationwide recall of griseofulvin oral suspension, a prescription medication used to treat ringworm and other fungal infections. The recall was issued based on two reports of glass fragments found in bottles of the liquid formulation. The recall is limited to the liquid

formulation of the medication and does not include any other dosage form. Consumers in possession of the medication should contact the pharmacy where they purchased the drug to determine if they have the product that has been recalled and direct medical questions to their healthcare professional.

Read the complete MedWatch 2007 Safety summary, including a link to the Firm's Press Release regarding this issue, at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Grifulvin>

MedWatch ... (4/10/2007) GlaxoSmithKline and the FDA informed healthcare professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen as Combivir and employed counterfeit labels for Combivir Tablets. Both medications are used as part of combination regimens to treat HIV+ infection. Two 60-count misbranded bottles of Combivir Tablets contained 300 mg tablets of Ziagen. The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California. Pharmacists should immediately examine the contents of each bottle of Combivir in their pharmacy to confirm that the bottles contain the correct medication. The Dear Pharmacy Professional Letter contains photos of actual Combivir and Ziagen Tablets. If a bottle contains anything other than Combivir Tablets, pharmacists should notify the manufacturer.

Read the complete MedWatch 2007 Safety summary, including a link to the firm's "Dear Pharmacy Professional Letter" regarding this issue, at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Ziagen>

FROM THE MEDICAL LITERATURE ...

Review of compliance studies ... A recent systematic review of medication adherence studies was not entirely encouraging. There were 37 studies reviewed and they were categorized into informational, behavioral, and combined. A major measure was the effect size of each study. Overall, although several types of interventions are effective few had an impact on clinical outcomes. The methods most effective appeared to be those that reduce dosing demands, and those that provided reinforcing information over several sessions. There were numerous limitations to the study as to how they selected studies to review, categorization of studies, and the difficulty in homogenizing, retrospectively, fairly disparate studies.

Kripalani S, Yao X, Haynes RB. Interventions to enhance medication adherence in chronic medical conditions: A systematic review. *Arch Intern Med.* 2007 Mar 26;167:540-550.

Good news for women and aspirin ... A large, prospective, case-controlled study of 79,439 women in the Nurse's Health Study was conducted over 24 years to assess risk of death due to cardiovascular disease or cancer, according to aspirin use. The conclusion was that low-to-moderate doses of aspirin had a positive benefit in lowering risk of particularly cardiovascular disease after 5 years, and somewhat less risk of cancer development after 10 years of aspirin use.



Chan AT, Manson JE, Feskanich D, Stampfer MJ, Colditz GA, Fuchs CS. Long-term aspirin use and mortality in women. *Arch Intern Med.* 2007 Mar 26;167:562-572.

Reviews of Note ...

- Clopidogrel: A review of its use in the prevention of thrombosis. *Drugs.* 2007;67(4):613-646.

- Patel PN, Pathak R. Rimonabant: A novel selective cannabinoid-1 receptor antagonist for treatment of obesity. *Am J Health-Syst Pharm.* 2007 Mar 1;64:481-489.
- Kimberlin DW, Whitley RJ. Varicella-Zoster vaccine for the prevention of herpes zoster. *N Engl J Med.* 2007 Mar 29;356(13):1338-1343.
- Hendeles L, Colice GL, Meyer RJ. Withdrawal of albuterol inhalers containing chlorofluorocarbon propellants. *N Engl J Med.* 2007 Mar 29;356(13):1344-1351.

FROM THE LAY LITERATURE about medicine ...

Tiping point for universal health care ... may be approaching. In two large articles, one based on an upcoming book, it describes the unusual alliance of liberal Democrats and CEO's of large companies coming together to push for some form of universal health care. Some of this is due to companies like Wal-Mart who have a competitive advantage because of their minimalist approach to providing health care, to the giant automakers who, due to union contracts have huge legacy expenses for retired workers. Although the motivations may be different, the driving force is the same: rising health care costs and insurance premiums. Big business apparently is desperate enough to invite the Congress to relieve them of some of the financial and bureaucratic burden. However, the current consensus appears to be that there will be 3 or 4 options. While there is a moral reasoning involved, marketplace competitiveness is also a key. Another concept that seems to be catching on is more attention paid to wellness. Its role in reducing health care consumption may get its day.



Cohn J. What's the one thing big business and the left have in common? *New York Times.* 2007 Apr 1.
http://www.nytimes.com/2007/04/01/magazine/01Healthcare.t.html?_r=1&ref=health&oref=slogin
 Freudenheim M. New urgency in debating health care. *New York Times.* 2007 Apr 6.
http://www.nytimes.com/2007/04/06/business/06schism.html?_r=1&ref=health&oref=slogin

Drugs in the water ... another warning article about pharmaceutical and personal care products (PPCP's) found in the water supply from disposal down the toilet, soaps and shampoos used, or even drug metabolites excreted. Part of the awareness is improved detection technology, so much of it has been there for a while. Surveys of streams across the country have detected residues from opiates, hormones, blood pressure drugs and antibiotics. Also, the baby boomers are brought into the conversation by virtue of their aging, taking more drugs, and thus even more drugs in the water. Some locales are offering alternative disposal options such as dropping off unused/outdated prescriptions at pharmacies or police stations (controlled substances) for disposal (eg, incineration). This is something we are likely to hear more about.



Vocabulary ... **Nocebo effect** ... “real, adverse physiological reactions people sometimes develop when they learn they have been exposed to something – even if there is no evidence it may be harmful.” This may play a key role in this saga. Personally, I'm drinking filtered water.

Dean C. Drugs are in the water. Does it matter? *New York Times.* 2007 Apr 3.
http://www.nytimes.com/2007/04/03/science/earth/03water.html?_r=2&ref=health&oref=slogin&oref=slogin

Update ...

Residencies and Resident numbers keep growing ... According to the American Society of Health-System Pharmacists (ASHP), more pharmacy students than ever will enter the rigorous postgraduate training offered by pharmacy residency programs, according to the results of the 2007 ASHP Resident Match Program. Of the 1900 that applied for the more than 1600 available

postgraduate year one residencies, 1300 were matched, a 31% increase. The majority were PGY1 residency positions; about 200 matched with PGY2 positions.

http://www.ashp.org/s_ashp/article_press.asp?CID=168&DID=2037&id=19381

AUBURN HSOP FACULTY in the literature ...

- Jackson CW. The role of second-generation antipsychotics in the treatment of psychotic disorders - editorial. *Am J Health-Syst Pharm.* 2007 Apr 15;64:815.

NEW RESOURCES in the DILRC ...

- Hale TW. *Medications and Mothers' Milk: A Manual of Lactational Pharmacology* 2006. 12th ed. Amarillo, TX: Hale Publishing, 2006.
- Olsen CG, Tindall WN, Clasen ME. *Geriatric Pharmacotherapy: A Guide for the Helping Professional.* Washington, DC: American Pharmacists Association, 2007.
- Lile JM, Miller DE, Rybicki AL, eds. *Pharmacy Certified Technician Training Manual.* 10th ed. Lansing, MI: Michigan Pharmacists Association, 2006.
- McEvoy GK, ed. *AHFS Drug Information 2007.* Bethesda, MD: American Society of Health-System Pharmacists, 2007.

TIMELY TOP TECH TIP ...

Big brother in the backseat ... “Black boxes” have been used in air planes for years to provide vital data after a crash. Now they may be used in the family car. The good news is that these devices can alert authorities in case of a crash and automatically send an emergency response team to a crash site, among other safety features (eg, GM’s *OnStar* system). These devices can also record a lot of data concerning the crash itself, such as direction, place of impact, speed, etc which can help emergency personnel more quickly and efficiently evaluate victims for needed trauma care. Now the bad news – who owns that data!?! It can just as easily be used to monitor driving and help prosecution in cases of potential negligence.



White JB. Will your automobile become a tattle-tale? *Wall Street Journal.* 2007 Mar 26.



The last “dose” ...

Ah, the paradise that awaits us in 1984! ... For every ill a pill. Tranquilizers to overcome angst, pep pills to wake us up, life pills to ensure blissful sterility. I will lift up mine eyes unto the pills whence cometh my help.

--Malcolm Muggeridge [1903-1990] British journalist, author, satirist

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

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