



## Key Inforbits

- 1 new drug and 5 MedWatches
- Cardiovascular statistics for women
- “Intermediate” class of drugs coming closer?
- All-nighters – more harm than good?
- Wash your hands!!!
- Interim recommendations for *H. flu* vaccine

## **NEW DRUGS, and other related stuff ...**

**New Drug** ... (12/17/2007) The FDA has approved **nebivolol (Bystolic™)** by Forest Laboratories, Inc. and Mylan Inc.) for the treatment of hypertension. It is dosed once daily and can be used alone or in combination with other hypertension treatments. Nebivolol is a selective beta 1 blocker at doses less than or equal to 10 mg per day and has the added pharmacological properties of producing vasodilation and reducing total peripheral resistance. Bystolic™ is supplied as 2.5, 5 and 10 mg tablets and the usual dose range is 5 to 40 mg once daily. The drug should be available in January 2008.

<http://www.bystolic.com/> [Manufacturer web site including package insert]

**MedWatch** ... (12/18/2007) The FDA issued a final rule that requires that manufacturers of over-the-counter stand-alone vaginal contraceptive and spermicidal products containing the chemical ingredient **nonoxynol 9 (N9)** include a warning that the chemical N9 does not provide protection against infection from HIV or other sexually transmitted diseases (STDs). Stand-alone spermicides include gels, foams, films, or inserts containing N9 are used alone for contraception. Additionally, N9 can irritate the vagina and rectum, which may increase the risk of contracting HIV/AIDS from an infected partner. Read the complete 2007 MedWatch Safety Summary including a link to the FDA Press Release regarding this issue at:

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

**MedWatch** ... (12/21/2007) The FDA issued an update concerning the **safe use of the fentanyl transdermal system (patch)**. The FDA previously issued a Public Health Advisory in July 2005. However, the Agency continues to receive reports of death and life-threatening adverse events related to fentanyl overdose when the fentanyl patch was used to treat pain in opioid-naive patients and when opioid-tolerant patients have applied more patches than prescribed, changed the patch too frequently, and exposed the patch to a heat source. The fentanyl patch is only for use in patients with persistent, moderate to severe chronic pain who have been taking a regular, daily, around-the-clock narcotic pain medicine for longer than a week and are opioid-tolerant. Patients must not expose the patch to excessive heat as this promotes the release of fentanyl from the patch and increases its absorption through the skin which can result in fatal overdose. Directions for prescribing and using the fentanyl patch must be followed exactly. Read the complete 2007 MedWatch Safety Summary including a link to the FDA Public Health Advisory and Information for Healthcare Professionals Sheet regarding this issue at:

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

**MedWatch** ... (12/21/2007) AM2 PAT, Inc., and the FDA informed healthcare professionals and consumers of a **nationwide recall of one lot of Pre-Filled Heparin Lock Flush Solution** (5 ml in 12 mL Syringes), Lot # 070926H. The heparin IV flush syringes have been found to be contaminated with *Serratia marcescens*, which have resulted in patient infections. This type of bacterial infection could present a serious adverse health consequence that could lead to life-threatening injuries and/or death. Consumers and user facilities should stop using the product immediately, quarantine the affected product, and return it to the distributor immediately. Read the entire 2007 MedWatch Safety Summary including a link to the manufacturer's press release regarding this issue at:

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

**MedWatch** ... (12/26/2007) Bayer Diabetes Care announced a voluntary market **recall of test strips (sensors)** used exclusively with the Contour TS Blood Glucose Meter. The test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5 - 17% higher test results. This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. There is no impact on the performance of strips with other Bayer meters. Check the lot number of the test strips in inventory and contact Bayer Diabetes Care for information regarding the return and replacement of strips. See the manufacturer's press release for specific product lot numbers affected by this recall. Read the complete 2007 MedWatch Safety Summary including a link to the manufacturer's press release regarding this issue:

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

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

**MedWatch** ... (12/27/2007) Cardinal Health announced a voluntary **recall for all Alaris Pump modules**, model 8100 (formerly known as Medley Pump module), shipped prior to September 27, 2007. The recall covers Alaris Pump modules that were distributed to 46 States, the District of Columbia, Canada, Guam, Puerto Rico and Saudi Arabia. The pump module was recalled because the unit may contain misassembled occluder springs that could lead to overinfusion that could result in serious adverse health consequences or death. Overinfusion may be difficult to detect because the misassembled springs can work intermittently, and there is no warning or notification of an overinfusion. See the manufacturer's press release for a list of the serial numbers for the devices affected by this recall and how the manufacturer will work with customers to minimize disruption while completing an inspection of the devices.

Read the complete 2007 MedWatch Safety Summary including a link to the manufacturer's press release regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#cardinal>

## **FROM THE MEDICAL LITERATURE ...**

**Top 10 papers according to the AHA** ... The American Heart Association's top two selections both deal with genome-wide associations for common diseases and coronary artery disease; others included documentation of the benefit of sodium restriction on cardiovascular disease outcomes; the COURAGE trial; two papers on stents and the underdiagnosis of hypertension in children and adolescents.

Top research advances include studies on genetics and stem cell research, stents. AHA News. 2007 Dec 20. From the American Heart Association 2007 year-end report.

<http://www.americanheart.org/presenter.jhtml?identifier=3052697>

**Cardiovascular statistics for women ...** A few eye-opening facts from the American Heart Association and the “Go Red for Women” campaign. For more data, visit the web site below.

- 1 in 3 adult females has some form of cardiovascular disease.
- Since 1984, cardiovascular disease death for females has exceeded those for males.
- In the U.S. in 2004, all cardiovascular diseases combined claimed the lives of 461,152 females while all forms of cancer combined to kill 265,013 females. Breast cancer claimed the lives of 40,539 females; lung cancer claimed 67,838.
- The 2004 death rate from cardiovascular disease was 288.6. Death rates were 239.3 for white females; 331.6 for black females.



[http://www.goredforwomen.org/healthcare\\_professionals/doc/H\\_MARKET\\_STA\\_WOMENA1.pdf](http://www.goredforwomen.org/healthcare_professionals/doc/H_MARKET_STA_WOMENA1.pdf)

**Intermediate class of drugs ...** The FDA held a public meeting in November to discuss the



possibility of creating an intermediate class of drugs that could be sold without a prescription, but only by a pharmacist. This concept has been discussed for many years (aka, third class of drugs, pharmacist-only drugs, behind-the-counter, transitional class), but has recently gained some traction. At least two recent articles have summarized various points of view on the topic and are worthy of review.

Traynor K. Pharmacists want FDA to create new intermediate drug category. *Am J Health-Syst Pharm.* 2008 Jan 1;  
Hussar D. Behind-the-Counter (BTC) long overdue but let's seize the day. *Pharmacist Activist.* 2007 Oct;2(10):1-2.

**Reviews of Note ...**

- Wu CM, McLaughlin K, Lorenzetti DL, Hill MD, Manns BJ, Ghali WA. Early risk of stroke after transient ischemic attack: A systematic review and meta-analysis. *Arch Intern Med.* 2007 Dec 10/24;167(22):2417-2422.
- Dumaine R, Borentain M, Bertel O, Bode C, Gallo R, White HD, et al. Intravenous low-molecular-weight heparins compared with unfractionated heparin in percutaneous coronary intervention: Quantitative review of randomized trials. *Arch Intern Med.* 2007 Dec 10/24;167(22):2423-2430.
- McVary KT. Erectile dysfunction. *N Engl J Med.* 2007 Dec 13;357(24):2472-2481.
- Davi G, Patrono C. Platelet activation and atherothrombosis. *N Engl J Med.* 2007 Dec 13;357(24):2482-2494.

**FROM THE LAY LITERATURE about medicine ...**

**All-nighter – more harm than good? ...** You've been told numerous times – its best to get



some sleep before a big test than to stay up all night studying. Now there's proof! A small study of 120 college students showed that those who had never stayed up all night studying had an average GPA of 3.1 compared to students who had stayed up all night, GPA 2.9. A similar study had similar findings. There is also no lack of anecdotal evidence supporting these findings. So, during exams if you are having an internal debate over whether to keep cramming or get some sleep ... choose the latter.

Virtanen M (Associated Press). Pulling all-nighters earns lower GPAs. *USA Today.* 2007 Dec 17.

[http://www.usatoday.com/tech/science/discoveries/2007-12-14-all-nighters-gpa\\_N.htm](http://www.usatoday.com/tech/science/discoveries/2007-12-14-all-nighters-gpa_N.htm)

**Wash your hands!! ...** A short article that does a nice job of making the case for washing hands to reduce transmission of various infections. Everyone knows the usual, washing hands after using the toilet, sneezing or before eating/handling food. Other, less advertised situations include after changing a diaper, cleaning up after a pet,



touching garbage cans, and cutting boards (in contact with raw food). Several examples are given that dramatically illustrate the effectiveness of this very simple procedure.

Pope TP. Why hand washing may be your best medicine. *New York Times*. 2007 Dec 19.

<http://well.blogs.nytimes.com/2007/12/19/why-hand-washing-may-be-your-best-medicine/>

**Health traps** ... Nine health traps are given with some explanation as to why. Several of these traps relate to health information on the Internet or prescription information. These serve to reinforce what many of us have been preaching for years. So, for those who seem to be skeptical of our advice (patients, students?!?) this may be a good “back up” resource. Some topics include: Web site information, real science vs. advertisement or testimonial, supplements, and physician samples.



Huget J. Nine traps to avoid; Tell us your No. 10. *Washington Post*. 2007 Dec 25; p. HE01.

[http://www.washingtonpost.com/wp-dyn/content/article/2007/12/21/AR2007122102133\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2007/12/21/AR2007122102133_pf.html)

### **Update ...**

#### **Interim recommendations for Haemophilus influenzae Type B (Hib) conjugate vaccines ...**

Certain lots of PedvaxHIB<sup>®</sup> (monovalent Hib vaccine) and Comvax<sup>®</sup> (Hib/hepatitis B vaccine) were voluntarily recalled by Merck & Co, Inc, due to potential contamination of vaccine (none has been found to be contaminated). Manufacturing was ceased and is not expected to resume until the fourth quarter of 2008. The following document gives interim vaccination recommendation in anticipation of the shortage of these vaccines.

Interim recommendations for Haemophilus influenzae Type B (Hib) conjugate vaccines related to the recall of certain lots of Hib-containing vaccines (PedvaxHIB<sup>®</sup> and Comvax<sup>®</sup>). *MMWR Dispatch*. 2007 Dec 19;56:1-2.

<http://www.cdc.gov/mmwr/pdf/wk/mm56d1219.pdf>

### **NEW RESOURCES in the DILRC ...**

- *PDR Concise Drug Guide for Pharmacists*. Montvale, NJ: Thomson Healthcare Inc, 2007.
- *PDR for Nonprescription Drugs, Dietary Supplements, and Herbs*. 29<sup>th</sup> ed. Montvale, NJ: Thomson Healthcare Inc, 2007.
- Lenz TL. *Lifestyle Modifications in Pharmacotherapy*. Baltimore: Lippincott Williams & Wilkins, 2008.



#### **The last “dose” ...**

People are so worried about what they eat between Christmas and the New Year, but they really should be worried about what they eat between the New Year and Christmas.

~Author unknown



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