

# AU InforMed

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## Key Inforbits

- CDC survey on obesity in adults in the U.S.
- HIV monitoring recommendations revised?
- IOM report released, the Future of Drug Safety
- Infants die due to drug error
- EBM vs. luck
- Einstein says ...

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

**MedWatch** ... Ortho and the FDA announced a revision to the prescribing information to inform of the results of two separate epidemiology studies that evaluated the risk of developing a serious blood clot in women using Ortho Evra<sup>®</sup> compared to women using a different oral contraceptive. The first study found that the risk of non-fatal venous thromboembolism (VTE) associated with the use of Ortho Evra<sup>®</sup> contraceptive patch is similar to the risk associated with the use of oral contraceptive pills containing 35 mcg of ethinyl estradiol and norgestimate. The second study found an approximate 2-fold increase in the risk of medically verified VTE events in users of Ortho Evra<sup>®</sup> compared to users of norgestimate-containing oral contraceptives containing 35 mcg of estrogen. Although the results of the two studies differ, the results of the second study support FDA's concerns regarding the potential for Ortho Evra<sup>®</sup> use to increase the risk of blood clots in some women. Prescribing information for Ortho Evra<sup>®</sup> continues to recommend that women with concerns or risk factors for thromboembolic disease talk with their healthcare professionals about using Ortho Evra<sup>®</sup> versus other contraceptive options.

Read the complete MedWatch 2006 Safety summary, including links to the Sponsor's updated prescribing information and the FDA's Q&As regarding this issue at:

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

**MedWatch** ... Safety-related drug labeling changes for August 2006 have been posted on the MedWatch website. The August 2006 posting includes 58 drug products with safety labeling changes to the Boxed Warning, Contraindications, Warnings, Precautions, or Adverse Reactions sections.

The Summary page --

[http://www.fda.gov/medwatch/SAFETY/2006/aug06\\_quickview.htm](http://www.fda.gov/medwatch/SAFETY/2006/aug06_quickview.htm)

-- provides drug names and a listing of the sections changed.

The Detailed view --

<http://www.fda.gov/medwatch/SAFETY/2006/aug06.htm>

-- includes sections/subsections changed and a description of new or modified safety information in the Boxed Warning, Contraindications, or Warnings sections. The full labeling may be accessed by clicking on the drug name in the detailed view.

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

**Wait and see** ... A study of 283 emergency room pediatric patients received either a “standard prescription” or a “wait-and-see” prescription for antibiotics to treat otitis media. The “wait-and-

see” prescription was to be filled only if the child had not improved or was worse in 48 hours. Analgesics and otic drops were standard. Upon follow up, substantially more parents reported not filling the antibiotic prescription than in the “standard” group (13% vs. 62%) with similar outcomes. The approach seems to be gaining ground.

Spiro DM, Tay K-Y, Arnold DH, Dziura JD, Baker MD, Shapiro ED. Wait-and-see prescription for the treatment of acute otitis media: A randomized controlled trial. *JAMA*. 2006 Sep 13;296(10):1235-41.

**Drug dispensing machines in physician offices** ... This is not a new story, but here is another technology entrepreneur inserting themselves into a medical maelstrom with, of course, patient care as the calling. In this scenario, the physician writes the Rx on his computer, prints it out, the patient takes it to a “staffer” who then fills it from an automated, prepacked machine. Two big points are made, that it increases the chances the patient will fill the Rx and get refills. Oh yes, it also increases the physician’s profit and removes the pharmacist from the equation. Hmmmm.



Sipkoff M. Automated dispensing machines hit doctors’ offices. *Drug Topics*. 2006 Sep 18.

<http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=372288>

**Obesity among adults** ... a new survey was released from the CDC identifying by state, the percentage of obese populations. The goal of  $\leq 15\%$  by 2010, set by *Healthy People 2010* appears to be off in the distance. As expected, Alabama is still ranked among the states with the highest incidence of obesity (25% to 29% category). The good news is that Louisiana and Mississippi are even worse! On a national level, **60.5% of the U.S. adult population are overweight**, 23.9% are obese, and 3% are extremely obese; men are more so than women. Also, as age rises, so does weight.

State-specific prevalence of obesity among adults – United States, 2005. *MMWR*. Sep 15;55(36):985-88.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5536a1.htm>

**HIV testing ... revised** ... A new report from the Centers for Disease Control and Prevention (CDC) has been released, revising recommendations for HIV testing. The biggest change is the recommendation that HIV screening be made a routine activity for all patients in a health-care setting (hospitals, ERs, clinics, correctional facilities, etc); the patients would still be able to “opt out” if they desired. The primary purpose is to better identify those patients with unidentified HIV infection, the numbers of which have not decreased in several years.



Branson BM, Handsfield HH, Lampe MA, Janssen RS, Taylor AW, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR*. 2006 Sep 22;55(RR-14):1-17.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>

**Varicella vaccine update** ... Among various provisional recommendations made by the Centers for Disease Control and Prevention (CDC), it is recommending two doses of varicella vaccine (for prevention of chickenpox) for all children <13 years old and a second “catch up” dose for children, adolescents and adults who have received only one previous dose.

ACIP provisional recommendations for prevention of varicella. June 2006, available at:

[http://www.cdc.gov/nip/vaccine/varicella/varicella\\_acip\\_recs\\_prov\\_june\\_2006.pdf](http://www.cdc.gov/nip/vaccine/varicella/varicella_acip_recs_prov_june_2006.pdf)

**Future of Drug Safety** ... The Institute of Medicine (IOM) released a report on September 22, 2006 (350 pp., \$46) addressing the future of drug safety, primarily centered around the Food and Drug Administration (FDA) and their involvement (or lack there of) in recent crises involving the pharmaceutical industry. High points of the report include: The FDA’s credibility has suffered recently; virtually everyone agrees improvements are needed; the FDA is seriously

underfunded; there is a breakdown of responsibility/accountability involving the FDA, the pharmaceutical industry and the public it serves. The entire report is available either in print or electronically.

Committee on the Assessment of the US Drug Safety System, Alina Baciuc, Kathleen Stratton, Sheila P. Burke, Editors *The Future of Drug Safety: Promoting and Protecting the Health of the Public*. Washington, DC: National Academy of Sciences, 2006.

<http://www.iom.edu/CMS/3793/26341/37329.aspx>

**Medication errors** ... ASHP Recommendations ... A recent medication error involving inappropriate doses of heparin to six infants led to the tragic deaths of three neonates in an Indiana hospital. The details regarding this event remain under investigation; however, the hospital has taken steps to prevent future occurrences by requiring double checks by pharmacists for all pulled inventory and validation of heparin doses for neonatal intensive care unit and pediatric intensive care unit patients by a minimum of two nurses. This unfortunate incident reemphasizes the need for reporting, quantification, classification, root-cause analyses, and the development of strategies for prevention of adverse medical events as mentioned in



Institute of Medicine reports. Please share the information with all who may benefit.

*The web links may require an ASHP membership.*

ASHP Recommendations:

<http://www.ashp.org/emplibrary/Med%20Error%20Member%20Update.pdf>

To read ASHP's statement on the incident, see

<http://www.ashp.org/news/ShowArticle.cfm?id=16881>.

### **Reviews of Note ...**

- American Diabetes Association. Nutrition recommendations and interventions for diabetes-2006: A position statement of the American Diabetes Association. *Diabetes Care*. 2006 Sep;29(9):2140-57.
- Doan T-L, Fung HB, Mehta D, Riska PF. Tigecycline: A glycylycylone antimicrobial agent. *Clin Ther*. 2006 Aug;28(8):1079-1106.
- Lindblad CI, Hanlon JT, Gross CR, Sloane RJ, Pieper CF, Hajjar ER, et al. Consensus Statement: Clinically important drug-disease interactions and their prevalence in older adults. *Clin Ther*. 2006 Aug;28(8):1133-43.

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

**Freshman 15 ... NOT ...** Daphne Oz, a junior at Princeton, has written yet another diet book, "The Dorm Room Diet: The 8-Step Program for Creating a Healthy Lifestyle Plan That Really Works" (Newmarket Press). This article is a plug for the book, but the brief information given indicates that there is a lot of common sense provided. It is summarized by the thoughts of - **make healthy eating choices, and moderation in everything else** -. Perhaps coming from "within" will resonate more with the intended audience.



Redfean S. Intro to college eating. *Washington Post*. 2006 Sep 12; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/09/11/AR2006091100841.html?referrer=email>

**EBM vs. Luck** ... An essay by a physician, gives some thought to a common conundrum in medicine, why do some patients thrive and others fail, when all else appears equal in regards to treatment, history, circumstances, etc? Why did Lance Armstrong survive his testicular, metastasized cancer when one-half of similar people who seemingly defy current conventional medical wisdom (eg, diet, exercise) survive to ripe old age? The answer: Luck!



Lerner BH. In science-based medicine, where does luck fit it? *New York Times*. 2006 Sep 19.

[http://www.nytimes.com/2006/09/19/health/19essa.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2006/09/19/health/19essa.html?_r=1&ref=health&oref=slogin)

**Unapproved drugs** ... Another article citing shortcomings of the FDA and their monitoring of unapproved drugs on the market. The primary defense is – insufficient resources! According to the article, approximately 2% of prescription drugs are unapproved, and the FDA says that physicians and pharmacists should beware – but they don't give much guidance as to how one should know one from another. Manufacturer's defense is, of course, it costs too much to go through the approval process (millions of dollars).

Rubin R. Hundreds of unapproved drugs sold by prescription. *USA Today*. 2006 Sep 18.

[http://www.usatoday.com/news/health/2006-09-17-unapproved-drugs-cover\\_x.htm](http://www.usatoday.com/news/health/2006-09-17-unapproved-drugs-cover_x.htm)

### **Update ...**

For students considering a residency, particularly P4's:

- Fotis MA. Advice for residency candidates going to the Midyear Clinical Meeting. *Am J Health-Syst Pharm*. 2006 Oct 1;63:1787, 1791.
- Marrs JC. Family medicine pharmacy residency programs. *Am J Health-Syst Pharm*. 2006 Oct 1;63:1803-5.

### **AUBURN HSOP FACULTY in the literature ...**

- Flynn EA, Barker KN. Effect of an automated dispensing system on errors in two pharmacies. *J Am Pharm Assoc*. 2006 Sep/Oct;46(5):613-15.



### **The last "dose" ...**

A clever person solves a problem.  
A wise person avoids it.

-- Albert Einstein [1879 - 1955]

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