

# AU InforMed

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## Key Inforbits

- Many, many MedWatches
- Who reads black boxes anyway?
- Girls are beating the boys, but it's a BAD thing
- \$100,000 for a year of treatment???
- "Social distancing"
- The five most unpopular jobs

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

**MedWatch** ... FDA issued a public health advisory to notify both healthcare professionals and consumers of recently published studies of serious renal and cardiovascular toxicity following **aprotinin (Trasylol<sup>®</sup>)** administration to patients undergoing coronary artery bypass grafting surgery (CABG). An observational study published in *The New England Journal of Medicine* reported that aprotinin may be associated with increased risk of myocardial infarction, stroke and renal dysfunction. *Transfusion* (on-line edition, January 20, 2006) has reported that aprotinin administration may increase the risk for renal toxicity. The risks and benefits associated with use of aprotinin in CABG are being evaluated. The FDA anticipates the public presentation of recent information and data at an advisory committee in the near future.

Read the complete MedWatch 2006 Safety summary, including links to the Public Health Advisory and supporting documents, at:

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

**MedWatch** ... The FDA issued a Public Health Advisory to notify healthcare professionals and patients about adverse events, including methemoglobinemia, associated with the use of **benzocaine sprays** used in the mouth and throat. Benzocaine sprays are used for locally numbing mucous membranes of the mouth and throat for minor surgical procedures or when a tube must be inserted into the stomach or airways. On February 8, 2006, the Veterans Health Administration (VA) announced the decision to stop using benzocaine sprays for these purposes. The FDA is aware of the reported adverse events and is reviewing all available safety data, but at this time is not planning action to remove the drugs from the market. The FDA is highlighting safety information previously addressed by the Agency (see link below), has provided other information for the consideration of clinicians in the PHA and will make further announcements or take action as warranted by the ongoing review.

Read the complete MedWatch 2006 Safety summary, including links to the Public Health Advisory and supporting FDA documents, at:

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

**MedWatch** ... FDA announced a **recall of all brands and sizes of Balanced Salt Solution (BSS)** manufactured by Cytosol Laboratories, Inc. because product lots were found to have elevated and dangerous levels of endotoxin. BSS is a drug used by health professionals to irrigate a patient's eyes, ears, nose and/or throat during a variety of surgical procedures including cataract surgery. FDA has also received complaints relating to injuries in over 300 patients who were

given BSS manufactured by Cytosol Laboratories The BSS products subject to the recall order were manufactured by Cytosol Laboratories, Inc. for distribution under three labels: "AMO Endosol" distributed by Advanced Medical Optics, Inc. (AMO), Santa Ana, Calif.; "Cytosol Ophthalmics" distributed by Cytosol Ophthalmics, Lenoir, NC; and "Akorn" distributed by Akorn, Inc., Buffalo Grove, Ill. Read the complete MedWatch 2006 Safety summary, including a link to the FDA Press Statement, at:  
<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Cytosol>

**MedWatch** ... BMS notified FDA and healthcare professionals about proposed changes to the prescribing information for **Tequin**<sup>®</sup> (**gatifloxacin**), including an updating of the existing WARNING on hypoglycemia and hyperglycemia, and a CONTRAINDICATION for use in diabetic patients. The changes also include other risk factors for developing hypo- and hyperglycemia, including advanced age, renal insufficiency, and concomitant glucose-altering medications while taking gatifloxacin. The proposed changes are highlighted in the following "Dear Healthcare Provider" letter issued by BMS. Specific wording of these additions and revisions to the labeling is pending FDA review and approval. Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare Professional letter and proposed revised label at:  
<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Tequin>

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

**Low fat is low down** ... in case you've just returned from a vacation on an isolated island, three recent articles from the Women's Health Initiative Randomized Controlled Dietary Modification Trial concluded that a low-fat diet did not significantly influence the risk of colorectal cancer, cardiovascular disease or invasive breast cancer. The references are listed below if you want more detail. Make that TWO eggs, please ...

- Prentice RL, Caan B, Chlebowski TR, Patterson R, Kuller LH, Ockene JK, et al. Low-fat dietary pattern and risk of invasive breast cancer: The Women's health initiative randomized controlled dietary modification trial. *JAMA* 2006 Feb 8;295(6):629-42.
- Beresford SAA, Johnson KC, Ritenbaugh C, Lasser NL, Snetselaar LG, Black HR, et al. Low-fat dietary pattern and risk of colorectal cancer: The Women's health initiative randomized controlled dietary modification trial. *JAMA* 2006 Feb 8;295(6):643-54.
- Howard BV, Van Horn L, Hsia J, Manson JE, Stefanick ML, Wassertheil-Smoller S, et al. Low-fat dietary pattern and risk of cardiovascular disease: The Women's health initiative randomized controlled dietary modification trial. *JAMA* 2006 Feb 8;295(6):655-66.



**Insurance coverage matters** ... A recent study assessed patient compliance based on the "tier" of drugs they received, eg, a typical 3-tier insurance system covers preferred drugs, generics, and nonpreferred drugs, with an escalation in co-pays of each. Lo and behold, the study showed that those patients receiving drugs from the top two tiers (cheaper) had improved adherence compared to those receiving the 3<sup>rd</sup> tier, or nonapproved (most expensive) drugs. Shrank WH, Hoang T, Ettner SL, Glassman PA, Nair K, DeLapp D, et al. The implications of choice: Prescribing generic or preferred pharmaceuticals improves medication adherence for chronic conditions. *Arch Intern Med* 2006 Feb 13;166:332-337.



**What black box???** ... An observational study of 51 outpatient practices was conducted to determine how many patients received a drug in violation of its black box warnings. Of over 300,000 patients, 0.7% received such a drug. They were more likely to be elderly or female.

Fortunately, <1% of these patients suffered an adverse effect. This supports other work that demonstrates the drug labels are not always read by prescribers!

Lasser KE, Seger DL, Yu DT, Karson AS, Fiskio JM, Seger AC, et al. Adherence to black box warnings for prescription medications in outpatients. *Arch Intern Med* 2006 Feb 13;166:338-344.

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

- Gruchalla RS, Pirmohamed M. Antibiotic allergy. *N Engl J Med*. 2006 Feb 9;354(6):601-609.
- Navarro VJ, Senior JR. Drug-related hepatotoxicity. *N Engl J Med*. 2006 Feb 16; 354(7): 731-9.
- Bray GM. Exenatide. *Am J Health-Syst Pharm* 2006 Mar 1;63:411-8.

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

**Girls are winning, or is it losing ...** Based on the 2004 National Survey on Drug Use and Health including 70,000 households, it appears that teenage girls are smoking cigarettes and marijuana, and drinking more alcohol than their male counterparts; this in addition to using more prescription drugs. Along with the basic problems of drug use, these girls are more prone to depression, addiction, and stunted growth. They are also more likely to contract STD's and become pregnant. We're not looking for gold medal performances in these categories.

Connolly C. Teen girls using pills, smoking more than boys: Governments findings counter overall decline.

*Washington Post.com* 2006 Feb 9; p. A03.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/02/08/AR2006020802228.html?referrer=email>

**Vocabulary ... Social distancing ...** a new, politically correct word for “quarantine.” This, and other concepts are discussed in this article concerning practical approaches to a flu pandemic. The “elbow bump” is suggested instead of the usual greeting of shaking hands. This is because it is much less likely that you would transmit a virus. Also, masks are effective. A couple of years ago, masks became a fashion statement in Taiwan, when every effort was made to contain the SARS outbreak. Unfortunately, the article makes the point that many measures are effective (eg, shut down mass transit) for a week or so, but over the long-haul of months that is impractical.

McNeil DG Jr. Greetings kill: Primer for a pandemic. *New York Times.com* 2006 Feb 12.

<http://www.nytimes.com/2006/02/12/weekinreview/12mcne.html>

**Pill books and pill sites ...** an author tries to make sense of the many sources of information on drugs aimed at consumers, books and web sites. This is a great article if you want to be confused. This is the article that patients should be waving in your face. While some of the advice is reasonable, others are born of misguided trust. If a patient were to ask you, “so, where is the best place to look for information about my drugs?” What would you tell them?

Duenwald M. So many pills, so little clarity. *New York Times.com* 2006 Feb 7.

[http://www.nytimes.com/2006/02/07/health/policy/07cons.html?\\_r=1&oref=slogin](http://www.nytimes.com/2006/02/07/health/policy/07cons.html?_r=1&oref=slogin)



**Stick'em up! Your money or your life ...** This isn't a phrase from a dark alley, it may be coming from your pharmacist, if you are unfortunate enough to need a newer drug for cancer. One drug in particular (at least at the moment) is Avastin<sup>®</sup> (by Genentech and Roche) who is seeking FDA approval for lung and breast cancer (it is currently approved for colon cancer). The manufacturer, although amazingly honest, but no less chilling, justifies the pricing of **\$100,000 per year**, not by the more traditional “cost of manufacturing, research and development” but by citing the “inherent value of life-sustaining therapies.” In other words, what is your life worth to

you? Co-pays (if the drug is covered) are estimated at \$10,000 to \$20,000 per year. Several other drugs are discussed that cost tens of thousands of dollars.

Berenson A. A cancer drug shows promise, at a price that many can't pay. *New York Times.com* 2006 Feb 15.

[http://www.nytimes.com/2006/02/15/business/15drug.html?pagewanted=1&\\_r=1](http://www.nytimes.com/2006/02/15/business/15drug.html?pagewanted=1&_r=1)

**Generic User Fees** ... Remember the article from last week, blasting the FDA for being so far behind in reviewing applications for generic drugs? The FDA is now announcing a program to charge the generic pharmaceutical companies user fees to process their applications, which in turn will allow the FDA to hire more reviewers to do it. This already happens for new drug applications, to great success (according to FDA). The generic drug industry is suspicious however, claiming FDA collusion with the "branded" industry to block approval of generics.

Kaufman M. FDA to explain need to charge fees for new generic drugs. *Washington Post.com* 2006 Feb 17; p. A08.

[http://www.washingtonpost.com/wp-](http://www.washingtonpost.com/wp-dyn/content/article/2006/02/16/AR2006021602211.html?referrer=email)

[dyn/content/article/2006/02/16/AR2006021602211.html?referrer=email](http://www.washingtonpost.com/wp-dyn/content/article/2006/02/16/AR2006021602211.html?referrer=email)

### Update ...

**5 most unpopular jobs** ... or in other words, the jobs with a high likelihood of shortages. The five jobs listed were nurse, machinist, librarian, truck driver and, 🎺 ta daa, **pharmacist!** This, of course, is no big shock to most of us, but it seems to be gathering increasing recognition. Sometimes, truck driver doesn't sound too bad ...

*submitted by Dr. Joe Keating*

<http://channels.netscape.com/careers/package.jsp?name=careers/pm/unpopularjobs>

### NEW RESOURCES in the DILRC ...

- *Mosby's Drug Consult for Health Professions*. St. Louis: Mosby/Elsevier, 2006.
- Ansel HC, Stoklosa MJ. *Pharmaceutical Calculations*. 12<sup>th</sup> ed. Baltimore: Lippincott Williams and Wilkins, 2006.
- United States Pharmacopeial Convention. *Drug Information for the Health Care Professional*. 26<sup>th</sup> ed. Vol. I. Greenwood Village, CO: Thomson Micromedex, 2006.
- United States Pharmacopeial Convention. *Advice for the Patient: Drug Information in Lay Language*. 26<sup>th</sup> ed. Vol. II. Greenwood Village, CO: Thomson Micromedex, 2006.
- United States Pharmacopeial Convention. *Approved Drug Products and Legal Requirements*. 26<sup>th</sup> ed. Vol. III. Greenwood Village, CO: Thomson Micromedex, 2006.
- National Center for Health Statistics. *Health, United States, 2005*. With Chartbook on Trends in the Health of Americans. Hyattsville, MD: 2005.



### The last "dose" ...

"One of the first duties of the physician is to educate the masses not to take medicine."

--Sir William Osler [1849-1919]

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