

# AU InforMed

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## Key Inforbits

- Several MedWatches and FDA warning
- Guideline update for strokes
- Many Americans can't pay for drugs
- Zebra's instead of horses?
- Specialty drugs are VERY expensive
- Drugs: Cause or cure?

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

**New Drug** ... (3/20/2008) The FDA has approved **bendamustine HCl (Treanda® by Cephalon)**. It is indicated for the treatment of chronic lymphocytic leukemia (CLL), a slowly progressing blood and bone marrow disease. The drug should be available in April. Bendamustine appears to act on several pathways, but the mechanism is not completely known. Another indication for treatment of indolent non-Hodgkins lymphoma is also under review. The drug has been granted orphan drug status which will provide Cephalon with marketing exclusivity for CLL until March 2015.

<http://www.treanda.com/> [Cephalon Press Release and prescribing information]

**MedWatch** ... (3/12/2008) FDA and Tibotec Therapeutics notified healthcare professionals of changes to the WARNINGS section of the prescribing information for **Prezista (darunavir) tablets regarding the risk of hepatotoxicity**. In clinical trials and postmarketing experience, drug induced hepatitis has been reported in patients receiving combination therapy with Prezista/ritonavir. Appropriate laboratory testing should be conducted prior to initiating therapy with Prezista/ritonavir and patients should be monitored during treatment. Increased AST/ALT monitoring should be considered in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pretreatment elevations of transaminases, especially during the first several months of Prezista/ritonavir treatment.

Read the complete 2008 MedWatch Safety Summaries including a link to the manufacturer's Dear Healthcare Professional Letter and Prescribing Information for Prezista concerning this issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Prezista>

**MedWatch** ... (3/12/2008) Amgen and the FDA notified healthcare professionals of changes to the Boxed Warnings/WARNINGS: **Increased Mortality and/or Tumor Progression section of the Aranesp and EPOGEN/PROCRIT labeling** to update information describing the results of two additional studies showing increased mortality and more rapid tumor progression in patients with cancer receiving ESAs. The prescribing information has been revised as follows: ESAs shortened overall survival and/or time to tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers when dosed to target a hemoglobin level of  $\geq 12$  g/dL.

Read the complete 2008 MedWatch Safety Summary including a link to the manufacturer's Dear Healthcare Professional Letter regarding this issue at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#ESA>

**MedWatch** ... (3/6/2008) The FDA advised healthcare professionals and consumers that the Agency issued Warning Letters to six U.S. companies and one foreign individual for marketing **unapproved and misbranded drugs over the internet to U.S. consumers for the prevention and treatment of sexually transmitted diseases (STDs)**. The products are marketed under the names Tetrasil, Genisil, Aviralex, OXi-MED, Imulux, Beta-mannan, Micronutrient, Qina, and SlicPlus. The products claim to prevent or treat a variety of STDs, including Herpes, Chlamydia, Human Papilloma Virus, cervical dysplasia, and HIV/AIDS. The products pose a serious health threat to unsuspecting consumers who don't know that these products are not FDA approved and have not been proven safe or effective. Read the complete 2008 MedWatch Safety Summary, including a link to FDA's News Release regarding this issue at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#STDs>

**MedWatch** ... (3/18/2008) Boehringer Ingelheim and FDA notified healthcare professionals that ongoing safety monitoring has identified a possible **increased risk of stroke in patients who take Spiriva**. This product contains tiotropium bromide. Boehringer Ingelheim reported to the FDA that it has conducted an analysis of the safety data from 29 placebo controlled clinical studies ("pooled analysis"). The preliminary estimates of the risk of stroke are 8 patients per 1000 patients treated for one year with Spiriva, and 6 patients per 1000 patients treated for one year with placebo. This means that the estimated excess risk of any type of stroke due to Spiriva is 2 patients for each 1000 patients using Spiriva over a one year period. The FDA has not confirmed these analyses; pooled analyses can provide early information about potential safety issues. Patients should not stop taking Spiriva HandiHaler before talking to their doctor. Read the complete MedWatch 2008 safety summary, including a link to the Early Communication, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Tiotropium>

**MedWatch** ... (3/21/2008) B. Braun Medical Inc. was notified by its supplier, Scientific Protein Laboratories LLC (SPL) of a **nationwide recall of Heparin Sodium USP** active pharmaceutical ingredient (API). The voluntary recall affects 23 Finished Product lots manufactured and distributed by B. Braun Medical Inc. nationwide and to Canada. One lot of Heparin Sodium, USP API acquired by B. Braun has a heparin-like contaminant. FDA has received reports of serious injuries and/or deaths in patients who have been administered Heparin injectable products of other companies containing this contaminant. Read the complete MedWatch 2008 safety summary, including a link to the Press Release, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#BBraun>

**FDA Alert** ... (3/21/2008) The FDA is highlighting the addition of information about **hepatotoxicity to the WARNINGS section of the Prezista® (darunavir ethalolate by Tibotec Therapeutics)** prescribing information. Prezista®, a protease inhibitor indicated for the treatment of human immunodeficiency virus (HIV) infection. Healthcare providers should conduct appropriate hepatic laboratory testing prior to and after starting patients on Prezista®. Patients should promptly seek medical attention if they experience unexplained fatigue, anorexia, nausea, jaundice, abdominal pain or dark urine. Healthcare professionals should consider interrupting or discontinuing Prezista® if evidence of new or worsening liver injury arises. For more information and other links go to: <http://www.fda.gov/cder/drug/infopage/darunavir/default.htm>

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

**Guideline update ...** for recommendations for **prevention of stroke in patients with stroke and transient ischemic attack (TIA)**. There are revised recommendations for antiplatelet



therapy. Also, patients with atherosclerotic ischemic stroke or a TIA but no known coronary heart disease should receive statin therapy "with intensive lipid lowering effects," according to new guidelines from the American Heart Association and American Stroke Association.

Adams RJ, Chair for the American Heart Association Science Advisory and Coordinating Committee. Update to the AHA/ASA recommendations for the prevention of stroke in patients with stroke and transient ischemic attack. *Stroke*. 2008;39:10.1161/STROKEAHA.107.189063.

<http://stroke.ahajournals.org/cgi/reprint/STROKEAHA.107.189063>

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

- Kent ME, Romanelli F. Reexamining syphilis: An update on epidemiology, clinical manifestations, and management. *Ann Pharmacother*. 2008 Feb;42(2):226-236.
- Rahman A, Isenberg DA. Systemic lupus erythematosus. *N Engl J Med*. 2008 Feb 28;358(9):929-939.
- Tapson VF. Acute pulmonary embolism. *N Engl J Med*. 2008 Mar 6;358(10):1037-1052.

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



**40% of Americans have trouble paying for drugs ...** A recent poll, conducted jointly by USA Today, the Kaiser Family Foundation, and Harvard School of Public Health showed that 40% of Americans struggle to afford prescription medications. It is a serious problem for 16%; 29% have not filled a prescription in 2 years due to cost and 23% say they have cut pills in half or skipped doses to conserve on prescription bills. Percentages were higher in those that lack insurance drug coverage, low income or taking more than four drugs regularly. Other topics covered were the public's perceptions of the pharmaceutical industry (negative overall) as related to advertising (1/3 asked their physician for a drug they saw advertised), safety of drugs (positive), value of new drug developments (positive), and the drug development process (50/50).

Four in 10 Americans say they have trouble paying for drugs or skip prescriptions or cut pills due to cost. Press Release. 2008 Mar 4. <http://www.hsph.harvard.edu/news/press-releases/2008-releases/poll-usa-today-kaiser-harvard-prescription-drugs.html>

**Physician, treat thyself ...** An opinion piece from a pediatric cardiologist that decries the state of physician education and training relative to time spent considering diagnosis, versus time spent considering treatment. His contention is that most diagnoses are relatively straightforward and that the zebra's are just that, rare. So why don't physicians concentrate their time in treating patients rather than waste so much time chasing obscure diagnoses?

It is a rhetorical question. He also takes a few jabs at the pharmaceutical industry, but interestingly, also at "recipe books" online, citing Up-to-Date, an electronic resource for diagnosis and treatment, calling it the "Cliff Notes for doctors." His summary is that physicians should spend more time updating themselves on the evidence for various treatment modalities rather than on molecular mechanisms of disease.



*Submitted by Dr. Wesley Lindsey.*

Sanghavi D. Training daze: Why do doctors fixate on diagnosis, not treatment? *Slate*. 2008 Mar 12.

<http://www.slate.com/id/2186446/>

**Drug costs rise, particularly ‘specialty drugs’** ... Another article pointing out that drug costs are rising faster than inflation or more than other medical costs. This is particularly true for the ‘specialty drugs’ which are typically biotech drugs for hard-to-treat diseases such as cancer, multiple sclerosis, etc and whose costs can exceed \$100,000 per year. Many big corporations (except pharmaceutical companies) are pushing for a generic drug bill so that it will be easier to manufacture and market less expensive versions of some of these drugs (biosimilars vs. biogenerics). There is also talk of imposing a “pay-for-performance” clause for expensive drugs. That is, if it doesn’t work, full price could not be charged – that is likely a long way off.



Chase M. Payers aim to rein in specialty-drug spending. Wall Street Journal. 2008 Mar 20; p. B1.

<http://online.wsj.com/article/SB120597290404750401.html?mod=djemHL> [subscription only]

**Gaucher disease needs ‘specialty drugs’** ... Cerezyme is an enzyme replacement for Gaucher disease, which afflicts only about 5000 people worldwide and about 1500 in the U.S. and it can be life-saving. However, Cerezyme can cost over \$400,000 per year. In two articles, light is shed on the debate over the cost of such drugs and why they are so expensive. According to these articles, the production costs for Cerezyme are only about 10% of the price charged. Also, criticism has been leveled at the company, Genzyme, for pushing the use of higher than needed doses, just for the sake of using more drug. Genzyme denies this and claims that drug can be obtained at no charge for those who can’t afford it. Genzyme has also established such a network, that it probably knows every patient in the world with the disease and has “cornered the market.” Also, even when an insurance program covers the product, the rates for the entire plan membership can be significantly affected.



Pollack A. Cutting dosage of costly drug spurs a debate. New York Times. 2008 Mar 16.

<http://www.nytimes.com/2008/03/16/business/16gaucher.html?ref=health>

Pollack A. Drug maker stays close to doctors and patients. New York Times. 2008 Mar 16.

<http://www.nytimes.com/2008/03/16/business/16gside.html?ref=health>

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

- Marlowe KF. Treating fibromyalgia requires a multidisciplinary approach. America’s Pharmacist. 2008 Mar;130(3):37-47.



### **The last “dose” ...**

*The medicine increases the disease.*

[La., Aegrescitque medendo.] – Virgil [70 BCE to 19 BCE] Classical Roman Poet

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*Bernie R. Olin, Pharm.D., Director*