

# AU InforMed

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## Key Inforbits

- Discontinuations of drugs and dose forms.
- Label revisions for Viagra® and relatives
- Big Pharma influence in Med Schools/trials
- No relief in kids under 6
- This drug is guaranteed!
- Don't fall for phishing

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

**New Drug** ... (10/17/2007) The FDA has approved **doripenem injection, 500 mg intravenous infusion (Doribax™** by Johnson and Johnson Pharmaceutical Research and Development, LLC), for the treatment of complicated urinary tract and intra-abdominal infections.

In several multi-center, multinational studies, doripenem was shown to have a cure rate comparable to levofloxacin, for complicated urinary tract infections, and meropenem, for complicated intra-abdominal infections. The most common adverse reactions reported were headache, nausea, diarrhea, rash, and phlebitis. In addition, allergic reactions have occurred and some may require immediate treatment.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01728.html>

<http://www.doribax.com/doribax/> [Manufacturer web site]

**New Drug** ... (10/16/2007) The FDA has approved **ixabepilone (Ixempra™** by Bristol-Myers Squibb) as monotherapy for the treatment of patients with metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine. The FDA has also granted approval of Ixempra™ in combination with capecitabine for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline, and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated. Ixempra™ is a microtubule inhibitor belonging to a class of antineoplastic agents, the epothilones. The drug should be available within days.

[http://newsroom.bms.com/index.php?s=press\\_releases&item=308](http://newsroom.bms.com/index.php?s=press_releases&item=308) [Bristol-Myers Squibb press release]

<http://www.ixempra.com/> [Bristol-Myers Squibb web site]

FDA News 2007 Oct 22. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01732.html>

**Discontinued Drug** ... (10/18/2007) Pfizer Inc. has announced that it is returning worldwide rights for Exubera® (insulin human [rDNA origin] inhalation powder) back to the developer, Nektar. This means that **Exubera® is discontinued from the market** by voluntary withdrawal due to poor market/sales performance. There will be a three-month transition period, after which the product will no longer be available.

Pfizer Dear Healthcare Provider letter, October 18, 2007.

[http://www.fda.gov/cder/drug/shortages/exubera\\_dear\\_doctor\\_letter.pdf](http://www.fda.gov/cder/drug/shortages/exubera_dear_doctor_letter.pdf)

**Discontinued Dose Form** ... (10/11/2007) Ortho Biotech Products, L.P. is discontinuing the injection dose form of Sporonox<sup>®</sup> (itraconazole). Final batches will expire in February 2008 and supplies are anticipated to be depleted by the end of the year. The oral forms of Sporonox<sup>®</sup>, oral solution and capsules will remain available. The package labeling for these products will be revised in the near future. (Personal Communication: Marc Kamin, MD, Chief Scientific Officer, Ortho Biotech Clinical Affairs, LLC, Letter, October 11, 2007, 1-888-227-5624).

**Label Revisions** ... (10/18/2007) The FDA has approved labeling changes for **erectile dysfunction (ED) drugs** in the class that includes Cialis<sup>®</sup>, Levitra<sup>®</sup>, and Viagra<sup>®</sup>, to display more prominently the potential risk of sudden hearing loss, and to guide consumers on what to do if they experience sudden problems with their hearing. In addition, the FDA plans to require the same changes in labeling for Revatio<sup>®</sup>, also a member of the drug class phosphodiesterase type 5 (PDE5) inhibitors. Revatio is used to treat pulmonary arterial hypertension (PAH). A very small number of patients taking the PDE5 inhibitors reported sudden hearing loss, sometimes accompanied by ringing in the ears and dizziness.

The label revisions can be viewed at: [www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm](http://www.fda.gov/cder/drug/DrugSafety/DrugIndex.htm).

For more information: [http://www.fda.gov/cder/drug/infopage/ed\\_drugs/QA.htm](http://www.fda.gov/cder/drug/infopage/ed_drugs/QA.htm)

FDA News 2007 Oct 18. <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01730.html>

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

 **The apple doesn't fall far from the tree** ... A national survey of department chairs in 125 accredited allopathic medical schools and 15 of the largest independent teaching hospitals across the U.S. resulted in returns of 459 out of 688 eligible chairs. Of those that responded (67%), 60% of department chairs had a personal relationship with the medical industry ranging from consultant to company founder. Looking at the administrative unit (department) 67% had some relationship. Clinical and nonclinical departments were culpable. The message is that this is a high percentage and that it needs to be managed and disclosed. Students pick up on such things, so is it any wonder that we see such pervasive industry influence in nonacademic settings? Although this is a study of medical schools, other health professions are not immune or exempt from such activities and influence. Campbell EG, Weissman JS, Ehringhaus S, Rao SR, Moy B, Feibelman S, Goold SD. Institutional academic-industry relationships. *JAMA*. 2007 Oct 17;298(15):1779-1786.

**Bias of reporting based on funding** ... Authors evaluated 275 studies funded by pharmaceutical companies and 229 studies that were not funded with industry money, whose aim was reporting and interpretation of adverse effects occurring with inhaled corticosteroids. Overall, finding statistically significant differences for adverse effects was significantly less frequent in studies funded by industry than those that were not. Part of the difference was study design and set up that favored the outcomes desired by the sponsors. The authors call for vigilance when reviewing study designs and for more thorough disclosure of conflicts of interest. Nieto A, Mazon A, Pamies R, Linana JJ, Lanuza A, Jiménez FO, et al. Adverse effects of inhaled corticosteroids in funded and nonfunded studies. *Arch Intern Med*. 2007 Oct 22;167(19):2047-2053.

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

- Lyseng-Williamson KA, Yang LPH. Topiramate: A review of its use in the treatment of epilepsy. *Drugs*. 2007;67(15):2231-2256.

- Carter NJ, Keating GM. Maraviroc. *Drugs*. 2007;67(15):2277-2288.
- Boucher BA, Hannon TJ. Blood management: A primer for clinicians. *Pharmacotherapy*. 2007 Oct;27(10):1394-1411.
- Kirkpatrick A, Rathbun S, Whitsett T, Raskob G. Prevention of central venous catheter-associated thrombosis: A meta-analysis. *Am J Med*. 2007 Oct;120(10):901-910.
- Shorr AF, ed. Management of venous thromboembolism. *Am J Med*. 2007 Oct;120(Suppl 10B):S1-S41. (6 articles)
- Abramowicz M, ed. Drugs for chronic obstructive pulmonary disease. *Med Lett Treat Guidelines*. 2007 Nov;5(63):95-100.

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

**FDA Panel Recommends Restriction on Cold Meds for Kids ...** (10/19/2007) Friday, an FDA Advisory Panel recommended banning the use of over-the-counter (OTC) cold products in children under age 6 years. The vote was two-fold: the Panel voted 21 to 1 to ban their use in children under 2 years old, but voted 13 to 9 for a ban in children aged 2 to 5 years. The Panel also voted 15 to 7 to all the continued marketing of these products in children 6 years old and older. This review was stimulated by Baltimore's Commissioner of Health petitioning the FDA due to several overdoses and deaths in children in the area. There was considerable dissension in the panel; also, the trade group Consumer Healthcare Products Association disagreed with the outcome of the votes. The pharmaceutical industry may well fight any ruling and official change could be years away. One article provides some tips for parents who want to avoid these products (*USA Today*).

Harris G. F.D.A. panel urges ban on medicine for child colds. *New York Times*. 2007 Oct 20.

[http://www.nytimes.com/2007/10/20/washington/20fda.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2007/10/20/washington/20fda.html?_r=1&ref=health&oref=slogin)

Stein R. Cold remedies are unproven for children, FDA panel says. *Washington Post*. 2007 Oct 20; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2007/10/19/AR2007101900246.html?wpisrc=newsletter>

Associated Press. Government advisers: don't use cold meds in kids under 6. *USA Today*. 2007 Oct 20.

[http://www.usatoday.com/news/health/2007-10-19-coldmeds\\_N.htm](http://www.usatoday.com/news/health/2007-10-19-coldmeds_N.htm)

**Guaranteed, or your money back ...** Part 2 ... In a previous issue of *AU InforMed* (July 20, 2007) the situation in Britain was mentioned where that government has created a situation where pharmaceutical companies must 'guarantee' that their drug works, or refund at least part of the money paid for it. This has been applied to very expensive drugs that may cost thousands of dollars. Other European countries apparently think this is a good idea as deals are being worked out with some drug companies (eg, Johnson & Johnson for Velcade<sup>®</sup> and Risperdal Consta<sup>®</sup>). This is being done in lieu of price decreases that the companies fear would spread world-wide. The frugality of European governments when paying for expensive drugs has led to flat or declining sales; their advantage is the monopoly governments have in regulating health care services and payment. There may be hope in the U.S. as at least one major insurer, Aetna, is exploring similar deals.



Pollack A. Pricing pills by the results. *New York Times*. 2007 Jul 14.

[http://www.nytimes.com/2007/07/14/business/14drugprice.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2007/07/14/business/14drugprice.html?_r=1&ref=health&oref=slogin)

Whalen J. Europe's drug insurers try pay-for-performance. *Wall Street Journal*. 2007 Oct 12; p. B1.

<http://online.wsj.com/article/SB119214458748556634.html?mod=djemHL> [subscription only]

**Pharmacists to the rescue, this time in Los Angeles ...** A story from Reuters describing pharmacist's positive involvement in community clinics serving some of the poorer areas of Los Angeles. The article also describes the rising tide of diabetics in the U.S. and the ease in which

they can receive less than the best care, partly due to access to limited resources and partly due to the disconnected health care system.

Submitted by Dr. Laura Smoot

Baertlein L. Los Angeles clinic shows flaws in diabetes care. *Reuters*. 2007 Oct 8.

<http://www.reuters.com/article/healthNews/idUSN8D36411920071008?feedType=nl&feedName=ushealth1100&pageNumber=1&sp=true>

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

- **Westrick SC, Felkey BG.** Pharmacy benefits management: What do employers need to know. *Alabama Pharmacy*. 2007 2<sup>nd</sup> Quarter, p. 18-19.
- **Duke JC.** Pandemic flu: Are you ready? *Alabama Pharmacy*. 2007 2<sup>nd</sup> Quarter, p. 27-28.

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

- Wynn RL, Meiller TF, Crossley HL. *Drug Information Handbook for Dentistry*. 13<sup>th</sup> ed. Hudson, OH: Lexi-Comp, Inc., 2007.
- Taketomo CK, Hodding JH, Kraus DM. *Pediatric Dosage Handbook*. 14<sup>th</sup> ed. Hudson, OH: Lexi-Comp, Inc., 2007.

### **TIMELY TOP TECH TIP ...**

**Don't fall for phishing ...** Advice from AU's Office of Information Technology: How can you tell if an e-mail message asking you to update account information is legitimate or a phishing attempt designed to snatch your personal information? When in doubt,



**Don't Click!** Here are a few ways you can tell: Phishing messages will appear urgent and they use dramatic language to get you to act now, so **Don't Click!**

They're not usually personalized but some can be. If they don't address you by name or you aren't sure, **Don't Click!** No one should be asking for your password,

PIN, social security number or bank information in an e-mail message, so **Don't Click!** Instead, go directly to the company's Web site by typing it in your browser or contact the company by phone to see if you really do need to take the action described in the e-mail message. October is National CyberSecurity Month.



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

"Glass, china, and reputations are easily cracked, and never well mended."

--Benjamin Franklin [1706 - 1790]

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