

# AU InforMed

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## Key Inforbits

- Zelnorm<sup>®</sup> back with limited availability
- PAD, clots and anticoagulants
- Plan B is doing well
- Drug use in the workplace rising?
- Congress looking at physician payments
- Ingredients of success

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

**Free Drugs** ... Publix supermarkets has announced a program in which it will give away seven antibiotics in 14-day supplies to those with valid prescriptions, regardless of insurance coverage. The antibiotics include amoxicillin, cephalexin, penicillin VK and erythromycin.

Associated Press. Publix to offer 7 popular prescription antibiotics for free. *USA Today*. 2007 Aug 6.

[http://www.usatoday.com/money/industries/health/2007-08-06-publix-free-antibiotics\\_N.htm](http://www.usatoday.com/money/industries/health/2007-08-06-publix-free-antibiotics_N.htm)

**Tamper-proof prescription pads** ... Once again, Congress has come to the rescue and just about everyone wishes they hadn't. Representatives Mike Ross, Marion Berry and Charlie Wilson are urging the Centers for Medicare and Medicaid Services (CMS) to delay implementation of a new federal mandate requiring the use of tamper-resistant prescription pads for all Medicaid prescription orders beginning **October 1, 2007**. Enacted as a cost-saving measure in the Emergency Supplemental Appropriations (Public Law 110-28), little time remains to educate prescribers, pharmacists and patients on this requirement, before pharmacists are forced to turn patients away for not presenting prescriptions on "approved tamper-resistant" paper. At this time CMS intends to comply with Congress' statutory guideline for implementation. APhA and others are urging all pharmacists to contact their legislators to remedy this impending disaster. APhA's home page address is below.

<http://www.aphanet.org//AM/Template.cfm?Section=Home>

**Name Change** ... Reliant Pharmaceuticals, Inc., has recently changed the name of OMACOR<sup>®</sup> to LOVAZA<sup>™</sup>. This was done at the request of the FDA and in response to reports of prescribing and dispensing errors due to similarity in name between the company's OMACOR<sup>®</sup> (omega-3-acid ethyl esters) capsules and Xanodyne Pharmaceuticals' Amicar<sup>®</sup> (aminocaproic acid). The name change is intended to minimize the potential for such errors in the future. Packaging bearing the name LOVAZA is available now.

[www.LOVAZA.com](http://www.LOVAZA.com) or [www.reliantrx.com](http://www.reliantrx.com)

### OMACOR

Current NDC (65726) Was Brand Name Pkg Size  
65726-0424-15 Was OMACOR60  
65726-0424-27 Was OMACOR120

### LOVAZA

Current NDC (65726) New Brand Name Pkg Size  
65726-0424-15 Is now LOVAZA60  
65726-0424-27 Is now LOVAZA120

**MedWatch** ... (7/20/2007) Baxter Healthcare Corp. and the FDA notified healthcare professionals and consumers of a Class I **Recall of Baxter Upgraded COLLEAGUE Triple Channel Volumetric Infusion Pumps**, Model numbers 2M8153, 2M8163, and 2M9163. The

product was recalled because a software irregularity causes the newly upgraded COLLEAGUE Triple Channel Volumetric Infusion Pumps to alarm, display an error code (16:310:867:0002) and stop the infusion. This occurs during user programming with all three channels infusing fluids at the same time. There are reports of serious injuries. In reported cases, the pump stopped infusing which caused it to activate an audible and a visual alarm. Interruption of life-sustaining therapy could lead to serious injury or death. Remove all the affected triple channel pumps from service immediately. COLLEAGUE customers with questions should contact Baxter Medical Delivery Services at 1-800-843-7867.

Read the complete MedWatch 2007 safety summary, including a link to the manufacturer's recall notice regarding this issue at:

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

**MedWatch** ... (7/27/2007) The FDA announced that it is **permitting the restricted use of Zelnorm<sup>®</sup> (tegaserod)** under a treatment investigational new drug (IND) protocol to treat irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in women younger than 55 who meet specific guidelines. In some instances, patients with a serious or life-threatening disease or condition who are not enrolled in a clinical trial may be treated with a drug not approved by the FDA. Generally, such use is allowed within guidelines called a treatment IND, when no comparable or satisfactory alternative drug or therapy is available. These patients must meet strict criteria and have no known or pre-existing heart problems and be in critical need of this drug. Zelnorm<sup>®</sup> (tegaserod) will remain off the market for general use. Physicians with IBS-C or CIC patients, who meet the IND criteria should contact Novartis at 888-669-6682 or 800-QUI-NTILE. Those who do not qualify for the Zelnorm<sup>®</sup> (tegaserod) protocol may contact FDA's Division for Drug Information about other options, 888-463-6332. Read the complete MedWatch 2007 Safety Summary including a link to the FDA News at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Zelnorm>

**MedWatch** ... (7/27/2007) Baxter Healthcare and the FDA notified healthcare professionals and consumers of a **Class I Recall of Baxter COLLEAGUE and FLO-GARD Volumetric Infusion Pumps**, Model numbers 2M8151 and 2M8153, COLLEAGUE CX Volumetric Infusion Pumps, Model numbers 2M8161 and 2M8163, and FLO-GARD Volumetric Infusion Pumps Model numbers 2M8063 and 2M8064. The products were recalled because the firm identified repair, inspection, and test data sheets, which included electrical safety data for the pumps, that were falsified. As a result it is possible that pumps sent to be serviced, repaired or corrected were returned without service being performed on them. This may result in over/under infusion, failure to detect an upstream or downstream occlusion, electrical shock hazard, failure to detect air in line and malfunctions where the pump will stop infusing and result in an interruption of therapy that can lead to death. Return affected pumps to Baxter Healthcare for repeat inspections and servicing. COLLEAGUE and FLO-GARD customers with questions should contact Baxter Healthcare Corp. at 1-800-422-4770.

Read the completed MedWatch 2007 Safety Summary including a link to the Recall notice at:

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

**MedWatch** ... (8/1/2007) The FDA announced that many consumers may not be aware of the May 2007 **recall of Complete MoisturePlus Multipurpose Contact Lens Solution** manufactured by Advanced Medical Optics (AMO) and continue to use the recalled product. Several cases of Acanthamoeba Keratitis have been reported to CDC that involve the use of AMO Complete MoisturePlus after the recall was announced. Individuals who wear soft contact lenses should stop using the Advanced Medical Optics Complete MoisturePlus product

immediately and discard all remaining solution, including unopened containers. See the FDA Preliminary Public Health Notification 5/31/2007, for recommendations for contact lens wearers. Read the complete MedWatch 2007 Safety Summary including a link to the FDA News Release and Preliminary Public Health Notification regarding this topic at:  
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#AMO>

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

**PAD and clots ...** A recent study measured the effectiveness and the risk of the use of antiplatelet therapy alone or combined with anticoagulant therapy in 2161 patients with peripheral arterial disease (PAD). Using morbidity and mortality endpoints over 35 months, the investigators determined that 132 of 1080 (12.2%) patients receiving combination antiplatelet/anticoagulant therapy, and 144 of 1081 (13.3%) patients receiving antiplatelet therapy alone suffered myocardial infarction, stroke or death from cardiovascular causes (relative risk, 0.92; 95% CI, 0.73 to 1.16; p=0.48). Life-threatening bleeding occurred in 43 patients receiving combination therapy (4%) compared to 13 patients receiving antiplatelet therapy alone (1.2%) ((relative risk, 3.41; 95% CI, 1.84 to 6.35; p<0.001). An accompanying editorialist comments on some of the ramifications of the results and potential mechanisms.

Warfarin Antiplatelet Vascular Evaluation Trial Investigators. Oral anticoagulant and antiplatelet therapy and peripheral arterial disease. *N Engl J Med.* 2007 Jul 19;357(3):217-227.

Mohler ER III. Atherothrombosis – Wave goodbye to combined anticoagulation and antiplatelet therapy? *N Engl J Med.* 2007 Jul 19;357(3):293-296.

**Risk of venous thrombosis estimated ...** A study was undertaken to estimate the magnitude of the risk of developing venous thromboembolism (VTE) in surgical and medical inpatients, based on the criteria of the Seventh American College of Chest Physicians (ACCP) Consensus Conference on Antithrombotic and Thrombolytic Therapy guidelines for VTE. Over 12 million patients (31%) of patients discharged from U.S. hospitals in 2003 were at risk for developing VTE. The question not answered by this study is how many of these patients are receiving the recommended VTE prophylaxis? An accompanying editorial lends another voice to the same question and emphasizes that this current study looks at only hospital inpatients. The question remains how many other patients outside of the hospital are also at risk and not receiving appropriate prophylaxis?

Anderson FA Jr, Zayaruzny M, Heit JA, Fidan D, Cohen AT. Estimated annual numbers of US acute-care hospital patients at risk for venous thromboembolism. *Am J Hematol.* 2007; DOI: 10.1002/ajh.20983.

Goldhaber SZ. Venous thromboembolism risk among hospitalized patients: Magnitude of the risk is staggering. *Am J Hematol.* 2007; DOI: 10.1002/ajh.20997.

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

- Simhan HN, Caritis SN. Prevention of preterm delivery. *N Engl J Med.* 2007 Aug 2;357(5):477-487.
- Spinewine A, Schmader KE, Barber N, Hughes C, Lapane KL, Swine C, Hanlon JT. Prescribing in elderly people 1. Appropriate prescribing in elderly people: How well can it be measured and optimized. *Lancet.* 2007;370:173-184.
- Mallet L, Spinewine A, Huang A. Prescribing in elderly people 2. The challenge of managing drug interactions in elderly people. *Lancet.* 2007;370:185-191.
- Hirsh J, O'Donnell M, Eikelboom JW. Beyond unfractionated heparin and warfarin: Current and future advances. *Circulation.* 2007;116:552-560.  
<http://circ.ahajournals.org/cgi/content/full/116/5/552>

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

**Plan B is doing just fine, thank you very much ...** Plan B sales have doubled since last August, when the FDA finally authorized the release of the product as an over-the-counter emergency contraceptive. Users of the product are happy for its availability and opponents are equally unhappy for its availability. The controversies and misunderstandings surrounding its release are still present and ongoing such as confusion over its actual mechanism (contraceptive vs. abortive agent), access due to providers moral objections, and assertions of the product's contribution to increased promiscuity. Hard data concerning actual decreases in unwanted pregnancy are yet to be gathered.

Stein R. Plan B use surges, and so does controversy. *Washington Post*. 2007 Jul 13; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2007/07/12/AR2007071202146.html?referrer=email>

**Drug use in the workplace ...** A new survey is out that shows 1 in 12 (8.2%) workers in the U.S. are active illicit drug users. Although the study was a snapshot and was not intended to show trends, similar studies in 1994 and 1997 showed a rate of 7.6% and 7.7%, respectively. Drug use was most common in the age range of 18 to 25 years (19%), and decreased with older ranges, being least in those 50 to 64 years (2.6%). Also, 2/3 of the users were men.

Survey: 1 in 12 U.S. workers using drugs. *USA Today*. 2007 Jul 16.

[http://www.usatoday.com/news/health/2007-07-16-drug-use\\_N.htm](http://www.usatoday.com/news/health/2007-07-16-drug-use_N.htm)

**Law requiring reporting of payments to physicians ...** It may be getting started. With so many reports appearing in the press and the medical literature, pharmaceutical company payments to physicians for services (real or imagined) have caught the attention of Congress. Senator Charles E. Grassley (R-Iowa) is proposing legislation requiring the companies to disclose payments made to physicians for services, presentations, and seminar attendance. This may have also been stimulated by the states of Minnesota, Vermont and Maine, who have already established such registries, and where much incriminating evidence has been found.

Harris G. Lawmaker calls for registry of drug firms paying doctors. *New York Times*. 2007 Aug 4.

[http://www.nytimes.com/2007/08/04/us/04drug.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2007/08/04/us/04drug.html?_r=1&ref=health&oref=slogin)

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

- **Wiley InterScience** – The HSOP Intranet, Online Resources now contains “The Cochrane Library.” This resource contains high-quality, independent evidence and includes Cochrane and other systematic reviews, clinical trials, and more. It is a great source of thoroughly researched reviews on a variety of topics.



### **The last “dose” ...**

“The three great essentials to achieve anything worth while are, first, hard work; second, stick-to-itiveness; third, common sense.”

--Thomas Edison, inventor and businessman [1847 - 1931]

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