

AU InforMed

Volume 5 Number 10 (Issue 145)

Friday, March 30, 2007



Key Inforbits

- New orphan drug – cethromycin
- Several significant MedWatch warnings
- HPV vaccine recommendations
- History of the Clinical Trial
- Exposure of kids to TV food ads
- 20/20 focused on medication errors

NEW DRUGS, and other related stuff ...

Withdrawn ... (3/30/2007) FDA is announcing that Novartis Pharmaceuticals has agreed to FDA's request that they **voluntarily discontinue marketing and sales of Zelnorm (tegaserod maleate)**. FDA's request was based on newly available information of an increased risk of serious cardiovascular adverse events, including myocardial infarction (heart attack), unstable angina (chest pain), and stroke, associated with use of the drug. Based on this new information, FDA has concluded that the overall risk versus benefit profile for the drug is unfavorable for continued marketing. More information is available at:
<http://www.fda.gov/cder/drug/infopage/zelnorm/default.htm>

New Orphan ... The FDA granted Orphan Drug Designation to **cethromycin** (by Advanced Life Sciences) for the prophylactic treatment of patients exposed to **inhalation anthrax** on March 14, 2007. The company's most advanced product candidate, cethromycin, is a second generation ketolide antibiotic in Phase III clinical development for the treatment of respiratory tract infections. Cethromycin has been tested in over 4,400 human subjects and is currently in Pivotal Phase III trials for the treatment of mild-to-moderate community acquired pneumonia (CAP). Cethromycin has also has significant in vitro activity against over 30 anthrax (*Bacillus anthracis*) strains. It is currently being tested in non-human primates to determine its potential efficacy for the prophylactic treatment of patients exposed to inhalation anthrax.

Advanced Life Sciences Holdings, March 14 /PRNewswire-FirstCall/

[http://phx.corporate-ir.net/phoenix.zhtml?c=190126&p=irol-](http://phx.corporate-ir.net/phoenix.zhtml?c=190126&p=irol-newsArticle&ID=973672&highlight=)

[newsArticle&ID=973672&highlight=](http://phx.corporate-ir.net/phoenix.zhtml?c=190126&p=irol-newsArticle&ID=973672&highlight=) [Advanced Life Sciences – Press Release]

<http://www.advancedlifesciences.com/portfolio/icd.htm> [Advanced Life Sciences – Cethromycin]

MedWatch ... (3/26/2007) Sanofi-Aventis issued a Dear Healthcare Professional letter for **Ketek® (telithromycin)**. The label has been revised to add a boxed warning and contraindication for **myasthenia gravis patients**. In addition, the indications for the treatment of acute exacerbation of chronic bronchitis and acute bacterial sinusitis have been removed from the labeling. In prescribing Ketek®, it is important for healthcare professionals to inform and discuss with patients the four highlighted toxicities: exacerbation of myasthenia gravis, hepatotoxicity, visual disturbances, and loss of consciousness. A Medication Guide has been developed that replaces the Patient Information section of the U.S. prescribing information for Ketek®, to better inform and educate patients. The Medication Guide must be provided by pharmacists to patients when Ketek® is dispensed. Healthcare professionals should advise patients to read the medication guide prior to taking Ketek®.

Read the complete MedWatch 2007 Safety summary, including a link to the Dear Healthcare Professional letter and the previous February 12 FDA MedWatch alert, at:

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

MedWatch ... (3/28/2007) Woodridge Labs and the FDA informed consumers and healthcare professionals of a recall of all lots of its **DermaFreeze365 Instant Line Relaxing Formula and DermaFreeze365 Neck and Chest products**. The products were recalled because certain lots tested positive for **Pseudomonas aeruginosa** bacteria. The bacteria may cause serious eye infections, urinary tract infections, respiratory system infections, dermatitis, soft tissue infections, bacteremia, bone and joint infections, gastrointestinal infections and a variety of systemic infections, particularly in patients with severe burns and in cancer and AIDS patients who are immunosuppressed. Because DermaFreeze365 Instant Line Relaxing Formula may be applied in the area of the eye, there is a possibility that if the recalled product is inadvertently introduced in the eye, it could result in serious eye infections and, in rare circumstances, possible blindness.

Read the complete MedWatch 2007 Safety summary, including a link to the manufacturer's press release regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#DermaFreeze365>

MedWatch ... (3/28/2007) The FDA notified consumers and healthcare professionals of a special webpage launched to **warn about the dangers of buying isotretinoin online**. Isotretinoin is a drug approved for the treatment of severe acne that does not respond to other forms of treatment. If the drug is improperly used, it can cause severe side effects, including birth defects. Serious mental health problems have also been reported with isotretinoin use. The new webpage, <http://www.fda.gov/buyonline/accutane>, will appear in online search results for Accutane (isotretinoin) or one of the generic versions, Amnesteem, Claravis, and Sotret. The webpage warns that the drug should only be taken under the close supervision of a physician or a pharmacist, and provides links to helpful information. The new webpage is in addition to special safeguards put in place by FDA and manufacturers of isotretinoin to reduce the risks of the drug, including a risk management program called iPLEDGE. The aim of iPLEDGE is to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin.

Read the complete MedWatch 2007 Safety summary, including a link to the FDA Accutane Product Information Page regarding this issue at:

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

MedWatch ... (3/29/2007) The FDA notified healthcare professionals and patients that companies that manufacture and distribute **pergolide** have agreed to **withdraw the drug from the market**. Pergolide is a dopamine agonist (DA) used with levodopa and carbidopa to manage the signs and symptoms of Parkinson's disease. Results of two new studies showed that some patients with Parkinson's disease treated with pergolide had serious damage to their heart valves when compared to patients who did not receive the drug. These two studies confirm earlier studies that also described this problem. Patients currently taking pergolide should contact their healthcare professional about alternate treatments and not abruptly stop taking their medication. Healthcare professions should assess their patient's need for DA therapy. If continued treatment with a DA is needed, another DA should be substituted for pergolide.

Read the complete MedWatch 2007 Safety summary, including a link to the FDA Public Health Advisory regarding this issue at:

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

FROM THE MEDICAL LITERATURE ...

ACIP Recommendations for HPV vaccine ... The CDC's Advisory Committee on Immunization Practices (ACIP) has issued their guidelines for the use of the quadrivalent human papillomavirus vaccine, licensed on June 8, 2006. The recommended age for the 3-dose vaccination is females aged 11 to 12 years; it can be given to girls as young as 9 years. Catch up vaccinations are recommended for females aged 13 to 26 years who have not been previously vaccinated. Much more information is in the 24-page report.

Quadrivalent human papillomavirus vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2007 Mar 23;56(RR-2):1-24.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm>

Drug interaction assessment tool ... Some drug interaction experts have proposed a new assessment tool to evaluate the validity of observed drug interactions in practice and in the literature. This tool follows a similar reasoning as the Naranjo algorithm for assessing adverse reactions, but much more tailored to potential drug interaction events; part of the rationale for its development was the lack of specificity of the Naranjo method for drug interactions. The Drug Interaction Probability Scale (DIPS) is intended to sort out drug interaction issues from others when evaluating patients; it is also intended to serve as an evaluation tool when reviewing articles for publication, or assessing already published drug interaction articles for validity.

Horn JR, Hansten PD, Chan L-N. Proposal for a new tool to evaluate drug interaction cases. *Ann Pharmacother*. 2007 Apr;41:xxxx. Online: www.theannals.com, DOI 10.1345/aph.1H423.

Reviews of Note ...

- Somogyi AA, Barratt DT, Collier JK. Pharmacogenetics of opioids. *Clin Pharmacol Ther*. 2007 Mar;81(3):429-444.
- White C. Intermittent claudication. *N Engl J Med*. 2007 Mar 22;356(12):1241-1250.
- Trost LW, Gur S, Hellstrom JG. Pharmacological management of peyronie's disease. *Drugs*. 2007;67(4):527-545.
- Waldinger MD. Premature ejaculation: Definition and drug treatment. *Drugs*. 2007;67(4):547-568.

FROM THE LAY LITERATURE about medicine ...

History of the Clinical Trial ... A great article for an introduction and brief history of the clinical trial as related to drug trials. There is a lot of information here that many of us would not know or at least tie together. Also, a timeline is provided to point out some major milestones along the way. Test: When was the "well-controlled" trial officially born?

Bren L. The advancement of controlled clinical trials. *FDA Consumer*. 2007 Mar/Apr;41(2):23-30.

http://www.fda.gov/fdac/features/2007/207_trials.html

Cancer chemotherapy side effects ... an insightful article from a professor treated for advanced prostate cancer and was rendered a drug-induced eunuch. Some good descriptions of the physical effects of such drug treatment, and perhaps more importantly, some rationales or coping mechanisms that might help you with your patients in similar situations.

Wassersug R. Disfiguring treatment? No, it was healing. *New York Times*. 2007 Mar 27.

http://www.nytimes.com/2007/03/27/health/27case.html?_r=1&ref=health&oref=slogin

Wellness starts with television ... The Kaiser Family Foundation has released results from the largest ever study of commercials aimed at children. Their results indicate (among other things) that children 8 to 12 years old see the most food ads on TV, an average of 21/day or 7600/year. Younger children of 2 to 7 years see the fewest at 12/day and adolescents see 17/day. Also, one-half of all advertising directed at children is for food. BUT WAIT, several major food and drink makers have agreed to voluntary new rules for advertising that will devote one-half of their advertising towards children to promote healthier diets and lifestyles. "I will gladly pay you Tuesday, ..." It is a very large and significant study. Gantz W, Schwartz N, Angelini JR, Rideout V. Food for thought: Television food advertising to children in the United States. Menlo Park, CA: Henry J. Kaiser Family Foundation, March 2007. <http://www.kff.org/entmedia/7618.cfm>



Update ...

A New Perspective: The State of Pharmacy in America. 2007 February. 33 pp. [A perspective from Walgreen's; it gives some interesting information, numbers and opinions on the state and direction of pharmacy. Two 2005 Auburn grads, **Shay and Tara Smith** are featured in a side bar on p. 3.]

AUBURN HSOP FACULTY in the literature ...

- Patry RA, **Eiland LS**. Addressing the shortage of pharmacy faculty and clinicians: The impact of demographic changes. *Am J Health-Syst Pharm.* 2007 Apr 1;64:773-775.
- **Lloyd KB**. Calcium supplementation for osteoporosis. *Pharmacy Times.* 2007 Mar;73(3):88,90,92.



The last "dose" ...

20/20

ABC's 20/20 show is airing a television segment tonight, 9:00 pm (CDT), Friday March 30, 2007 concerning medication errors and featuring pharmacists, not necessarily in a positive light. Auburn University researchers, lead by **Dr.'s Kenneth Barker, Betsy Flynn and Bruce Berger** were asked to design a study for ABC to use to obtain data related to medication error rates. Many details are yet to be revealed, so be sure to watch!



Also, this Sunday, April 1, **60 Minutes** (CBS at 6:00 pm CDT) will run a segment about the prescription drug lobby. The segment focuses on how the drug lobby's enormous clout distorted the purposes of the new Medicare drug legislation and resulted in a prohibition that prevents Medicare from bargaining for more reasonable drug prices, among other topics.

An electronic bulletin of drug and health-related news highlights, a service of ...

Auburn University, Harrison School of Pharmacy, Drug Information Center

• Phone 334-844-4400 • Fax 334-844-8366 • <http://www.pharmacy.auburn.edu/dilrc/dilrc.htm>

Bernie R. Olin, Pharm.D., Director