

# AU InforMed

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## Key Inforbits

- New drugs and indications.
- Drug trend report 2004.
- Hurricane preparedness.
- Meth mouth again.
- Automobiles and patient care?
- Students in the literature.

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

**New Vaccine** ... for pertussis ... The FDA approved a new vaccine for a single booster immunization against pertussis (whooping cough), in combination with tetanus and diphtheria, for adolescents and adults 11-64 years of age, on June 10, 2005. The vaccine will be marketed as Adacel™ by Aventis Pasteur Limited located in Toronto, Canada. Adacel™ is a Tetanus Toxoid (T), Reduced Diphtheria Toxoid (d) and Acellular Pertussis Vaccine (ap), Adsorbed. Adacel™ contains the same components as Daptacel®, a DTaP vaccine indicated for infants and children manufactured by Aventis Pasteur Limited, but the diphtheria toxoid and one of the pertussis components are in reduced quantities. Recently, FDA approved a similar vaccine called Boostrix®, manufactured by GlaxoSmithKline, for use in adolescents 10-18 years of age. FDA. FDA approves a new combination vaccine to help protect both adolescents and adults against whooping cough. *FDA Talk Paper* 2005 Jun 10;T05-24.

<http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01361.html> (FDA)

<http://www.sanofipasteur.com/sanofi-pasteur/front/templates/vaccinations-travel-health-vaccine-aventis-pasteur.jsp?&lang=EN&codeRubrique=13&codePage=ADACEL0605> (Sanofi Pasteur)

**New Drug** ... The FDA has approved galsulfase (Naglazyme™ by BioMarin Pharmaceutical), for the first specific treatment of mucopolysaccharidosis VI (MPS VI). The disease, also known as Maroteaux-Lamy syndrome, is a lysosomal storage disease that affects approximately 1100 people, worldwide. The manufacturer plans to launch it in the United States this summer.

<http://www.naglazyme.com/>

**New Indication** ... The FDA approved sildenafil citrate tablets (Revatio™ by Pfizer, and perhaps better known as Viagra®) on June 6, 2005, for treatment of patients diagnosed with pulmonary arterial hypertension (PAH). It is indicated for early stages of the disease and is the first oral therapy available. PAH is estimated to affect about 100,000 people worldwide.

[http://www.pfizer.com/pfizer/are/news\\_releases/2005pr/mn\\_2005\\_0606.jsp](http://www.pfizer.com/pfizer/are/news_releases/2005pr/mn_2005_0606.jsp)

**New Indication** ... and **launch date** ... The FDA approved new indications for Lyrica™ (pregabalin by Pfizer) of adjunctive treatment of partial onset seizures in adults with epilepsy. Lyrica™ was approved last December for diabetic peripheral neuropathy and postherpetic neuralgia, but the company has been awaiting a DEA ruling on its schedule. It appears the DEA will soon classify it as a schedule V. Pfizer expects to launch the product this fall.

[https://www.lyrica.com/pdf/USApprovalRelease\\_Epilepsy.pdf](https://www.lyrica.com/pdf/USApprovalRelease_Epilepsy.pdf)

**New Dose Form** ... **ZMax™** ... Pfizer received approval for ZMax™ a single dose, extended release, oral azithromycin for acute bacterial sinusitis and community-acquired pneumonia in adults. It should appear in pharmacies in July, in plenty of time for the upcoming winter season. It is to be priced similarly to the multiple-dose product now, and of course, the timing has nothing to do with loss of patent protection of the older dose forms this coming November.  
[http://www.pfizer.com/pfizer/are/news\\_releases/2005pr/mn\\_2005\\_0613c.jsp](http://www.pfizer.com/pfizer/are/news_releases/2005pr/mn_2005_0613c.jsp)

**MedWatch** ... Sustiva® (efavirenz) Capsules and Tablets ... Bristol-Myers Squibb and FDA notified healthcare professionals of revisions to the WARNINGS, PRECAUTIONS/Pregnancy and Information for Patients, and PATIENT INFORMATION sections of the prescribing information for Sustiva® (efavirenz), indicated in the treatment of HIV-1 infection. The revisions are a result of four retrospective reports of neural tube defects in infants born to women with first trimester exposure to Sustiva®, therefore, pregnancy should be avoided in women receiving Sustiva®. An antiretroviral pregnancy registry has been established to monitor fetal outcomes of pregnant women exposed to Sustiva®.  
<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Sustiva>

**MedWatch** ... The FDA has requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAIDs) make proposed labeling changes to their prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products including Celebrex® (celecoxib), a COX-2 selective NSAID. Labeling revisions include a boxed warning, highlighting the potential for increased risk of cardiovascular events and the potential life-threatening gastrointestinal (GI) bleeding. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. Read the complete MedWatch 2005 Safety summary, including a link to the updated Drug Information Page and Medication Guide, at:  
<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#NSAID>

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

 **Drug Trend Report 2004** ... Express Scripts just released their Drug Trend Report for 2004. Among other things it showed that prescription drug spending halted its climb in 2004, for sponsors of drug benefit programs that adopted two or more cost-management programs. It largely centers around generic drug use over brand names. For access to the complete 159 page report go to the home page below and find the link to Drug Trend Report.  
<http://www.express-scripts.com/>

**Lindane repackaging** ... **NOT** ... Cases of unintentional lindane ingestion are on the decline, but the Centers for Disease Control and Prevention (CDC) is reminding pharmacies to dispense the pesticide only in the 1- and 2-ounce single-use containers provided by the manufacturers. For more information, go to:  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5421a2.htm>

 **Hurricane preparedness** ... Those of us in Alabama received an early wake up call about hurricanes last week. You know they are nothing to mess with. The CDC has a web site with a variety of recommendations for being prepared. Read it early and often!  
<http://www.bt.cdc.gov/disasters/hurricanes/index.asp>

**Flu vaccine shortage ...** It's official. Chiron Corp, the manufacturer whose manufacturing facility in England was shut down last year, is predicting producing fewer doses this year. Due to delays in restarting its plant, the company is predicting to produce 18 to 25 million doses, down from the initial estimate of 25 to 30 million. It is unknown how or if, this will affect upcoming flu vaccination programs this fall.

Press release from Chiron Corp, June 15, 2005.

<http://phx.corporate-ir.net/phoenix.zhtml?c=105850&p=irol-newsArticle&ID=720791&highlight=>

### Reviews of Note ...

- *APhA Pharmacy Student*, 2005 May/June issue.  
Whole issue is devoted to the "business" of pharmacy; several perspectives on potential careers, clinical and otherwise, written primarily by Pharm.D./MBA's.
- Abramowicz M, ed. Drugs for hypertension. *Treatment Guidelines Med Lett*. 2005 Jun;3(34):39-48.
- Peters KR. Review of the current asthma guidelines for the United States, Great Britain, and the World. *Advances in Pharmacy*. 2005;3(2):143-55.
- Miller MG, Lucas D Jr, Papademetriou V, Eihabyan A-K. Aspirin under fire: Aspirin use in the primary prevention of coronary heart disease. *Pharmacotherapy*. 2005 Jun;25(6):847-61.

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

 **Medical book ...** You may hear about a new medical "self-help" book, *You: The Owner's Manual*. The authors promote five lifesaving activities: controlling blood pressure; avoiding tobacco; exercising 30 minutes per day; managing stress; and adhering to a healthy diet. Good ideas, but hardly groundbreaking. So, why all the buzz and why did it sell over 1 million copies in just a few days? It was promoted on Oprah's show!

Szabo L. Medical self-help guide is a surprising best seller. *USA Today* 2005 Jun 8.

[http://www.usatoday.com/news/health/2005-06-08-self-help\\_x.htm](http://www.usatoday.com/news/health/2005-06-08-self-help_x.htm)

 **Meth mouth ...** You may recall an article in *AU InforMed* a few months ago concerning this topic. "Meth mouth" is the result of methamphetamine use and its effects on/in the oral cavity, particularly the teeth. Here is another one, with more detail of the devastation. Apparently there are pockets of the country where this is becoming very common and typically the dental decay is so severe that extraction and dentures are the only option.

Davey M. Grisly effect of one drug: 'Meth mouth.' *New York Times.com* 2005 Jun 11.

<http://www.nytimes.com/2005/06/11/national/11meth.html?pagewanted=1>

 **Toyota to the rescue of patient care ...** A hospital in Seattle took a lesson from an automobile manufacturing plant to improve patient care. It's a rather mundane story in a way, but the improvements in patient care by applying assembly line technology, some basic efficiencies and a few environmental niceties, dramatically improved patient satisfaction AND saved money!

Connolly C. Toyota assembly line inspires improvements at hospital. *Washington Post.com* 2005 Jun 3; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2005/06/02/AR2005060201944.html?referrer=email>

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

- Gay VF, Dowling BK. The Auburn University Academy of Student Pharmacists. *Alabama Pharmacy* 2005 Spring;38:11.
- Alabama Pharmacy Association's Legislative Day (Student picture with Governor Riley). *Alabama Pharmacy* 2005 Spring;38:21.

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

Malone PM. New specialized search tools from Copernic and Google. *Advances in Pharmacy*. 2005;3(2):156-66.

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

"Knowing is not enough; we must apply.  
Willing is not enough; we must do."  
- Goethe [1749 - 1832]



**Happy Flag Day, June 14, 2005**

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