

# AU InforMed

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## Key Inforbits

- 3 New Drugs
- Several new generics
- Which came first, compliance or health?
- Economics of new drugs and generics
- Disturbing news about MySpace.com
- Tattoo's

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

**New Drug** (biologic) ... On June 30, 2006 the FDA approved a new biologic agent, **ranibizumab (Lucentis™ by Genentech)** injection, for the treatment of neovascular (wet) age-related macular degeneration (AMD). It is an injection administered into the eye at monthly intervals. It was effective in 95% of patients, compared to 60% in the control group. Most serious adverse events were related to the ophthalmic injection procedure.

FDA approves new biologic treatment for wet age-related macular degeneration. *FDA News*. 2006 Jun 30; P06-94.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01405.html>

<http://www.lucents.com/lucents/index.jsp?fontsize=dec> (Genentech web site)

**New Drug** ... The FDA granted accelerated approval for **dasatinib (Sprycel™ by Bristol-Myers Squibb Co)**, a new oral treatment for chronic myeloid leukemia (CML), on June 29, 2006. Regular approval was granted for adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph + ALL). The drug was also granted Orphan Drug status for both indications due to the limited number of patients with either of the diseases. Dasatinib is intended to be used after other standard therapies have failed. Estimated cost for the 140 mg daily dose is \$47,000 per year.

Bristol-Myers gets FDA's approval for leukemia drug. *Wall Street Journal*. 2006 Jun 29; p. B6.

FDA gives rapid approval for a new treatment for a rare type of leukemia. *FDA News*. 2006 Jun 29; P06-89.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01400.html>

[http://www.bms.com/news/press/data/fg\\_press\\_release\\_6582.html](http://www.bms.com/news/press/data/fg_press_release_6582.html) (Bristol-Myers Squibb web site)

**New Drug** ... **Darunavir (Prezista™ by Tibotec, Inc)** was approved by the FDA on June 23, 2006. As a HIV-1 protease inhibitor, and in combination with ritonavir, it is indicated for the treatment of HIV-1 infections in antiretroviral experienced patients. It is contraindicated in co-administration with drugs that are highly dependent on CYP3A for clearance. These include some antihistamines (terfenadine, astemizole), ergot derivatives, cisapride, pimozone, midazolam and triazolam. Dosing is 600 mg (two 300 mg tablets) twice daily.

<http://www.tibotec.com/news/list.jhtml> (Tibotec web site and press releases)

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/> (Drugs@FDA web site, includes label)

**New Generics** ... Four new generics were approved the week of June 19, 2006. The most significant was simvastatin (Zocor® by Merck) as it is the second most popular statin prescribed. Some are estimating significant savings as the switch is made from the more expensive trade

names to the less expensive generics. Three other drugs that now have approved generic counterparts are finasteride tablets, 1 mg (Propecia<sup>®</sup>); finasteride tablets 5 mg (Proscar<sup>®</sup>); and lamotrigine tablets (Lamictal<sup>®</sup>).

FDA approves first generic simvastatin: fourth new generic approved this week. FDA News. 2006 Jun 23;P06-84. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01394.html>

**MedWatch** ... The FDA announced that it completed its safety assessment of Ketek<sup>®</sup> (telithromycin), indicated for the treatment of acute exacerbation of chronic bronchitis, acute bacterial sinusitis and community acquired pneumonia of mild to moderate severity, including pneumonia caused by resistant strep infections. The drug has been associated with rare cases of serious liver injury and liver failure with four reported deaths and one liver transplant. The FDA determined that additional warnings are required; package labeling is being revised. The FDA is advising both patients and physicians to be on the alert for signs and symptoms of liver problems. Patients experiencing such signs or symptoms should discontinue telithromycin and seek medical evaluation, which may include tests for liver function.

Read the complete MedWatch 2006 Safety summary, including links to the FDA news release and previous alerts, at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Ketek2>

**MedWatch** ... Boehringer Ingelheim and the FDA informed healthcare professionals of important new safety information for Aptivus<sup>®</sup> (tipranavir) capsules, co-administered with ritonavir (500mg/200mg), that includes an addition to the drug's Black Box Warning regarding reports of both fatal and non-fatal intracranial hemorrhage (ICH). Boehringer Ingelheim identified 14 reports of intracranial hemorrhage events, including 8 fatalities, in 6,840 HIV-1 infected individuals receiving tipranavir capsules in combination antiretroviral therapy in clinical trials. No patterns of abnormal coagulation parameters were observed. Routine measurement of coagulation parameters is not currently indicated with tipranavir. An increased risk of ICH was previously observed in patients with advanced HIV-1 disease/AIDS.

Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare Professional Letter and revised prescribing information at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Aptivus>

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

**Compliance = Healthy?? Healthy = Compliance??** ... Taking recommended medications on schedule, even placebos, cuts patients' risk of near-term death, according to a meta-analysis in a recent issue of the *British Medical Journal*. The report suggests that patients who are compliant with their medications take better overall care of themselves than do less-adherent patients, to the point that good adherence behavior is a surrogate marker for overall healthy behavior.

Simpson SJ, Eurich DT, Majumdar SR, Padwal RS, Tsuyuki RT, Varney J, et al. A meta-analysis of the association between adherence to drug therapy and mortality. *BMJ*, doi:10.1136/bmj.38875.675486.55 (published June 21, 2006)



<http://bmj.bmjournals.com/cgi/content/full/333/7557/0>

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

- Kasbekar N. Tigecycline: A new glycyclcline antimicrobial agent. *Am J Health-Syst Pharm*. 2006 Jul 1;63:1235-43.

- Strunk RC, Bloomberg GR. Omalizumab for asthma. *N Engl J Med*. 2006 Jun 22;354(25):2689-95.
- Top 200 drugs used in hospitals in 2005. *Drug Topics*. 2006 Jun 19;150(12):HSE12.

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

**Vocabulary** ... A recent survey by the Partnership for a Drug-Free America stated that 19% of U.S. teenagers have taken prescription analgesics and stimulants. This is a dramatic change over the last few years, when it was relatively uncommon. Of course, it has its own vernacular. “**Pharm Party**” is not a kegger outside of town, but parties where teens down handfuls of pills. The bowls or baggies full of various tablets/capsules are called “**trail mix.**” Where do all of these things come from? “**Pharming,**” which is the raiding of the family medicine cabinet to contribute to the pharm party. Strangely enough, even prescription drugs have an aura of safety about them and many teens believe that since these are approved pharmaceuticals, they must be safe! The article also describes several deaths due to these fatal misconceptions.

Leinwand D. Prescription drugs find place in teen culture. *USA Today*. 2006 Jun 12.

[http://www.usatoday.com/news/health/2006-06-12-teens-pharm-drugs\\_x.htm](http://www.usatoday.com/news/health/2006-06-12-teens-pharm-drugs_x.htm)

**Economics** ... In addition to the pricing of the new drug, **dasatinib (Sprycel™ by Bristol-Myers Squibb Co)** at \$47,000 per year (see article on p. 69), there is other economic news. A drug recently approved for multiple myeloma, **Revlimid® by Celgene**, will be priced at \$6195 per month or >\$74,000 annually. Although not in the thousands, the new HPV vaccine (**Gardasil® by Merck**) is to be priced at \$360 for the 3-shot regimen, making it the most expensive vaccine on the market. The pay-off could be huge, but its not something we will know for perhaps decades; it’s estimated that to vaccinate just 12 year-old girls, the costs to insurers may be \$700 million. Finally, Big Pharma is getting tired of having their patents expire and generic companies come in and take their profits. Some companies (Pfizer is highlighted in the article) are creating spinoff companies to produce and market the generic version of their trade name product. Called “**authorized generics**” it retains more profit for the innovator company and aggravates the generic companies, which according to Pfizer’s CEO, “both are good things.”



Anand G. Celgene to price cancer medicine at \$6,195 a month. *Wall Street Journal*. 2006 Jul 1; p. A4.

Wang S. HPV vaccine stirs economic debate. *Wall Street Journal*. 2006 Jun 29; p. D4.

Hensley S. Pfizer to make generic version of Zolof. *Wall Street Journal*. 2006 Jun 29; p. B1.



**Is it the shampoo** ... A paper presented at a recent Endocrine Society’s conference reported that various shampoos, soaps, and lotions containing lavender and tea tree oils may cause gynecomastia in boys, due to hormone imbalance. These oils may mimic estrogen action and reduce androgen activity. Everyone agrees that this is speculation, based on five case reports. However, keep this in mind in case such a scenario is presented in your practice.

Ghassemi JG. Bad shampoo for boys? *Washington Post.com* 2006 Jul 5; p. HE02.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/07/03/AR2006070300769.html?referrer=email>

**My[drug]Space.com** ... As if parents don’t have enough to worry about, the highly popular online social networking site MySpace.com (90 million members, 20% under 18 y/o) may have “groups” that promote drug use, self-mutilation, etc, up to sales and marketing. All sorts of

“sales pitches” can take place to young people and risk taking behaviors can be promoted by the unscrupulous or stupid. The other similar sites (eg, Facebook.com) are just as likely. For those uninitiated into these web sites, this is something to read. Add it to your “list of things to talk about” with your kids, or perhaps, yourself.

Payne JW. Invitation to harm. *Washington Post*. 2006 Jul 4; p. HE04.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/07/03/AR2006070300788.html?referrer=email>

### Update ...



For those students contemplating a residency, here is a recent article that recounts one former pharmacy resident's rationale and experience:

Weant KA. On being a pharmacy resident. *Am J Health-Syst Pharm*. 2006 Jul 1;63:1230-1.

### TIMELY TOP TECH TIP ...

**ID Theft** ... It used to be that we only worried about the security of software systems to protect privacy from hackers. Now in addition, we have to worry about the stupidity, incompetence or greed of those with legal access to our private data. What should you do if you suspect you are a victim of identity theft? Speed, organization and documentation are paramount to reduce real or potential damage.



- Report it immediately to one of the three major credit bureaus and request a 90-day fraud alert. The company you call is required to contact the other two.
- If you have evidence of actual fraud, file a report with the local police (get a copy of the report for future reference).
- Alert the credit bureaus and credit issuers of fraudulent activity, in writing.

There is much more information in the article, at the web site below.

Krebs B. Be prepared for ID theft: A quick response helps. *Washington Post*. 2006 Jun 18; p. F01.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/06/17/AR2006061700106.html?referrer=email>



### The last “dose” ...



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**% of 18-29 year olds with a tattoo or a body piercing (other than the ear lobe)**

Bridges A. Survey: 24% between 18-50 tattooed. *USA Today*. 2006 Jun 11.

[http://www.usatoday.com/news/health/2006-06-11-tattoo-survey\\_x.htm](http://www.usatoday.com/news/health/2006-06-11-tattoo-survey_x.htm)

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