

AU InforMed

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Key Inforbits

- New drug for colorectal cancer
- Another maker of flu vaccine
- Patient counseling breakdowns
- New isn't necessarily better!
- Phenylephrine dissatisfaction coming?
- Report those "statin" side effects

NEW DRUGS, and other related stuff ...

New Drug ... The FDA approved panitumumab (Vectibix™ by Amgen Inc) on September 27, 2006 for the treatment of patients with colorectal cancer that has metastasized following standard chemotherapy. It is a monoclonal antibody that binds to a protein called epidermal growth factor receptor or EGFR on some cancer cells. Panitumumab received an accelerated approval after showing effectiveness in slowing tumor growth and, in some cases, reducing the size of the tumor. In the U.S. it is estimated that 150,000 new cases of colon cancer will be diagnosed and 55,000 deaths will occur from colon and rectal cancer in 2006. Approximately 70% of all colorectal carcinomas are EGFR positive. As part of the approval, Amgen committed to conduct a postmarketing trial to show whether the drug improves patients' survival in patients with fewer prior chemotherapies. In addition, the drug is priced at \$4000 per dose for roughly a few additional months of life.

FDA approves a new drug for colorectal cancer, Vectibix. *FDA News*. 2006 Sep 27; P06-148.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01468.html>

http://www.amgen.com/media/media_pr_detail.jsp?releaseID=909842 [Amgen press release]

Pollack A. Amgen prices colon cancer drug 20% below Imclone rival. *New York Times*. 2006 Sep 28.

http://www.nytimes.com/2006/09/28/business/28drug.html?_r=1&ref=health&oref=slogin

New Flu Vaccine ... The FDA approved FluLaval® (manufactured by ID Biomedical Corporation of Quebec, Canada, a subsidiary of GlaxoSmithKline Biologics, distributed by GlaxoSmithKline), October 5, 2006, to immunize people 18 years of age and older against the disease caused by strains of influenza virus judged likely to cause seasonal flu in the Northern Hemisphere in 2006-2007. There are now five FDA-licensed vaccines for the U.S. for the upcoming influenza season. According to the Centers for Disease Control and Prevention (CDC), the manufacturers have projected making a total of about 115 million doses of influenza vaccine for the 2006–2007 season, but these projections could change as manufacturing continues. According to CDC, every year in the U.S., on average: 5% to 20% of the population gets seasonal flu; more than 200,000 people are hospitalized; and about 36,000 people die.

FDA approves additional vaccine for upcoming influenza season. *FDA News*. 2006 Oct 5; P06-156.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01478.html>

New Dose Form ... The FDA approved fentanyl buccal tablets (Fentora™ by Cephalon) on September 25, 2006, for the management of breakthrough pain in patients with cancer who are already receiving, and who are tolerant to opioid therapy for their underlying persistent cancer

pain. Its proprietary OraVescent[®] drug delivery system was developed by Cephalon subsidiary CIMA LABS; Fentora[™] is covered by patents until 2019. It is a Schedule II product.
<http://www.fentora.com/hcp/default.aspx> [Manufacturer web site; press release; prescribing information]

MedWatch ... Genentech and FDA announced revisions to the WARNINGS and ADVERSE REACTIONS sections of the prescribing information concerning 1] cases of a rare brain-capillary leak syndrome [reversible posterior leukoencephalopathy syndrome (RPLS)] and 2] postmarketing reports of nasal septum perforation. RPLS is a neurological disorder associated with hypertension, fluid retention and cytotoxic effects of immunosuppressive drugs on the vascular endothelium. The syndrome can present with headache, seizure, lethargy, confusion, blindness and other visual and neurologic disturbances. Mild to severe hypertension may be present, but is not necessary for diagnosis. The onset of symptoms has been reported to occur from 16 hours to 1 year after initiation of **Avastin**. Magnetic Resonance Imaging (MRI) is necessary to confirm the diagnosis of RPLS.

Read the complete MedWatch 2006 Safety summary, including links to the Sponsor's Dear Healthcare Provider Letter and updated prescribing information regarding this issue at:
<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Avastin>

MedWatch ... The FDA announced preliminary information from the North American Antiepileptic Drug Pregnancy Registry that suggests that babies exposed to lamotrigine (Lamictal[®] by GlaxoSmithKline), indicated to treat seizures and bipolar disorder, during the first three months of pregnancy may have a higher chance of being born with a cleft lip or cleft palate. Women who are pregnant and taking Lamictal[®] or who are thinking about taking it are urged to not start or stop taking the medication without first talking to their physician.

Read the complete MedWatch 2006 Safety summary, including links to the FDA Patient Information Sheet and Healthcare Professional Information, regarding this issue at:
<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Lamictal>

MedWatch ... FDA and Bristol-Myers Squibb notified pharmacists and physicians of **revisions to the labeling for Coumadin[®] (warfarin)**, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients. The 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.

Information about all currently approved Medication Guides is available at:

http://www.fda.gov/cder/Offices/ODS/medication_guides.htm

Read the complete MedWatch 2006 Safety summary, including links to the new Medication Guide, revised prescribing information and supplemental supporting documents, at:

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

MedWatch ... FDA and the **iPLEDGE program** announced an update to iPLEDGE, a risk management program to reduce the risk of fetal exposure to isotretinoin, that will eliminate one element of the program, the 23 day lock-out period for males and females of non-child bearing potential. This change does not affect female patients of child-bearing potential.

Read the complete MedWatch Safety summary, including links to the Dear Healthcare professional letter and supplemental FDA information, at:

<http://internet-dev/medwatch/safety/2006/safety06.htm#Isotretinoin>

FROM THE MEDICAL LITERATURE ...

Physician, listen to thyself ... From a variety of physician practices in California an observational study, using surveys and transcribed audiotapes of office visits, measured the quality of physician communication when prescribing new medication. On a scale of 5, the average score was 3.1. They did best on the easy stuff (eg, name, purpose) and worst on adverse effects and administration information. Clearly this is a problem for patients. Pharmacy should be easily covering this gap, but are we??



Tarn DM, Heritage J, Paterniti DA, Hays RD, Kravitz RL, Wenger NS. Physician communication when prescribing new medications. *Arch Intern Med.* 2006 Sep 25;166:1855-62.

Old drugs better than new ones?? ... In a study of 227 patients in England that required a change in therapy for schizophrenia, quality of life scores, symptoms, adverse effects, participant satisfaction and costs of care were recorded. Blind assessments were made at 12, 26 and 52 weeks of therapy. Therapies were the second generation (atypical) antipsychotics and the first generation (typical) antipsychotics (clozapine was excluded). Results showed that quality of life scales and symptom scores improved with the first generation antipsychotics, costs were similar and patients had no overall preference. Another important point for this study, it was not funded by any commercial enterprise.

Jones PB, Barnes TRE, Davies L, Dunn G, Lloyd H, Hayhurst KP, et al. Randomized controlled trial of the effect on quality of life of second- vs first-generation antipsychotic drugs in schizophrenia. *Arch Gen Psychiatry.* 2006 Oct;63:1079-87.

Two commentaries were also published in the same issue, both from the U.S. Both were interesting in that they were lamenting both the state of antipsychotic therapy (ie, if the second generations aren't any better, then we haven't progressed very far over a half century).

Lieberman JA. Comparative effectiveness of antipsychotic drugs. *Arch Gen Psychiatry.* 2006 Oct;63:1069-72.

Rosenheck RA. Outcomes, costs, and policy caution. *Arch Gen Psychiatry.* 2006 Oct;63:1074-6.

Children vulnerable to flu ... In a recent report by state, the CDC indicated that in the 2004-2005 influenza season, the percentage of children fully vaccinated ranged from 3.3% to 35.5%. This was the first year for a full recommendation for vaccination for the age group of 6-23 months and approximately double of the previous year. The point is also made that protection of children is also enhanced when household contacts and caregivers are also vaccinated.



Childhood influenza vaccination coverage – United States, 2004-05 influenza season. *MMWR.* 2006 Oct 6;55(39):1061-65.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5539a1.htm>

Reviews of Note ...

- Zhang J, Ding EL, Song Y. Adverse effects of cyclooxygenase 2 inhibitors on renal and arrhythmia events: Meta-analysis of randomized trials. *JAMA.* 2006 Oct 4;296(13):1619-1632.
- McGettigan P, Henry D. Cardiovascular risk and inhibition of cyclooxygenase: A systematic review of the observational studies of selective and nonselective inhibitors of cyclooxygenase 2. *JAMA.* 2006 Oct 4;296(13):1633-1644.
- Vroom F, de Walle HEK, van de Laar MAJF, Brouwers JRBJ, de Jong-van den Berg LTW. Disease-modifying antirheumatic drugs in pregnancy: Current status and implications for the future. *Drug Safety.* 2006;29(10):845-63.

FROM THE LAY LITERATURE about medicine ...

Phenylephrine dissatisfaction ... A recent article reporting on apparent patient dissatisfaction with the pseudoephedrine replacement drug, phenylephrine. Due to recent federal (and state) legislation, pseudoephedrine is now more difficult to purchase, amounts and times are limited, all in an effort to reduce availability of a methamphetamine precursor. Phenylephrine has become the decongestant of choice to replace it. The problem is, it may not be as effective, at least in the recommended dose, and has a shorter duration. The data is based on an FDA review in 1976; new studies are underway, but prepare for patient complaints about phenylephrine products.



Kritz FL. Allergy season switch: Some say new formulations don't work well. *Washington Post*. 2006 Sep; p. HE01. <http://www.washingtonpost.com/wp-dyn/content/article/2006/09/25/AR2006092500926.html?referrer=email>

Statin side effects ... The "statins" have been around awhile now, but the medical community is still concerned about their adverse effects. The point is made that even though numerous studies show their benefit, studies specifically designed to determine risk are underrepresented. One group from the University of California-San Diego feels that patient complaints may not meet with the proper concern from practitioners, so they have set up a web site specifically for patients to report side effects of "cholesterol" drugs. Their primary aim is to try to determine the real incidence of adverse effects of these drugs. The web site is www.statineffects.com
Parker-Pope T. Researchers ask patients to help fill gap in data on side effects of statins. *Wall Street Journal*. 2006 Oct 3; p. D1.

AUBURN HSOP FACULTY in the literature ...

- Berger B, Braxton Lloyd K. Communication concerning sensitive issues: Counseling on erectile dysfunction. *US Pharm*. 2006 Aug;31(8):96, 98, 100, 102.

NEW RESOURCES in the DILRC ...

- Bartlett JD, ed. *Ophthalmic Drug Facts 2006*. St. Louis: Facts and Comparison/Wolters Kluwer Health, 2006.
- DerMarderosian A, Beutler JA, ed. *The Review of Natural Products*. 4th ed. St. Louis: Facts and Comparison/Wolters Kluwer Health, 2005.



The last "dose" ...

"As the pie gets smaller, the table manners get worse."

William Zellmer, quoting Henri Manasse (both of ASHP).
Actual author unknown.

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