

AU InforMed

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Key Inforbits

- 3 new drugs approved
- A number of MedWatches ...
- Report on birth defects
- Superfluous research?
- More conflicts of interest
- Birth defects prevention month

NEW DRUGS, and other related stuff ...

New Drug ... The FDA approved **lenalidomide** (Revlimid[®] by Celgene Corp.) for the treatment of patients with a subtype (deletion 5q cytogenetic abnormality) of Myelodysplastic Syndrome (MDS) on December 28, 2005. MDS is a collection of disorders in which the bone marrow does not function normally and the body does not make enough normal blood cells. Patients with MDS may need blood and platelet transfusions and antibiotic therapy for infections. Patients treated with lenalidomide may no longer need transfusions, with most patients becoming independent of transfusion by three months. The transfusion-free period lasted for an average of 44 weeks. An estimated 7,000 to 12,000 new cases of MDS are diagnosed each year in the US. Lenalidomide is structurally similar to thalidomide, a known teratogen. It is unknown whether lenalidomide poses similar risks. Until that time, the company is marketing the drug under a risk management plan "RevAssist," intended to prevent fetal exposure. Also, the drug will be expensive, \$4,500 and \$4,700 a month, or about \$54,000 to \$56,400 annually. The company's justification is that it will be cheaper than transfusions.

<http://www.revlimid.com/> (Celgene Corp. web site)

FDA. FDA approves new treatment for myelodysplastic syndrome (MDS). *FDA News* 2005 Dec 28; P05-114.

<http://www.fda.gov/cder/drug/infopage/lenalidomide/default.htm>

Anand G. Company Puts a Big Price Tag On Drug to Treat Blood Disease. *Wall Street Journal* 2005 Dec 29; D2.

New Drug ... **Abatacept** (Orencia[®] by Bristol Myers Squibb) was approved by the FDA on December 23, 2005. It is in the domain of human cytotoxic T-lymphocyte-assisted antigens and is derived by recombinant DNA technology. It is indicated for adult patients with moderately to severely active rheumatoid arthritis with inadequate response to other DMARDs. The drug is administered via IV infusion, approximately every four weeks.

http://www.orencia.com/orencia/home/index.jsp?BV_UseBVCookie=Yes (Company information and labeling)

New Drug ... **Conivaptan HCl** injection (Vaprisol[®] by Astellas Pharma US) was approved by the FDA on December 30, 2005. Conivaptan is an arginine vasopressin antagonist, indicated for the treatment of euvolemic hyponatremia in hospitalized patients. It may also be approved for hypervolemic hyponatremia in the near future. It is administered intravenously as a loading dose then a continuous infusion, generally over 1 to 3 days.

http://www.astellas.us/press_room/press_releases.php (Astellas press release)

MedWatch ... The FDA notified healthcare professionals and patients that it issued warning letters to nine companies marketing bogus flu products behind claims that their products could be effective against preventing the avian flu or other forms of influenza. FDA (or anyone else, for that matter) is not aware of any scientific evidence that demonstrates the safety or effectiveness of these products for treating or preventing avian flu and the agency is concerned that the use of these products could harm consumers or interfere with conventional treatments.

Read complete MedWatch 2005 Safety summary, including a link to the FDA press release, at: <http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#avian>

MedWatch ... GlaxoSmithKline and FDA notified healthcare professionals about post-marketing reports of new onset and worsening diabetic macular edema for patients receiving rosiglitazone. In the majority of these cases, the patients also reported concurrent peripheral edema. In some cases, the macular edema resolved or improved following discontinuation of therapy and in one case, macular edema resolved after dose reduction.

Read the complete MedWatch 2006 Safety summary, including a link to the GSK Dear Healthcare Professional letter, at:

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

MedWatch ... Safety-related drug labeling changes for October 2005 have been posted on the MedWatch website. The September 2005 posting includes 43 drug products with safety labeling changes to Contraindications, Boxed Warning, Warnings, Precautions, or Adverse Reactions.

Summary page -- http://www.fda.gov/medwatch/SAFETY/2005/oct05_quickview.htm

-- provides drug names and a listing of the sections changed.

Detailed view -- <http://www.fda.gov/medwatch/SAFETY/2005/oct05.htm>

-- includes sections/subsections changed and a description of new or modified safety information in the Contraindications, Boxed Warning, or Warnings sections. The full labeling may be accessed by clicking on the drug name in the detailed view.

MedWatch ... Cangene, Baxter Healthcare and FDA notified healthcare professionals of revisions to the Warnings, Precautions and Adverse Reactions sections of the prescribing information to address two important safety concerns.

1] Postmarketing safety surveillance has shown rare, but severe and sometimes fatal, intravascular hemolysis and potentially serious complications, including disseminated intravascular coagulation in patients with ITP.

2] Maltose in IVIG products, such as the liquid formulation of WinRho SDF[®], has been shown to give falsely high blood glucose levels in certain types of blood glucose testing systems. Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific should be used to test or monitor blood glucose levels in patients receiving this product.

Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare Professional letter, revised label and patient information at:

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

FROM THE MEDICAL LITERATURE ...



Birth defects ... A new report from the CDC based on data from a program, the National Birth Defects Prevention Network (NBDPN), that estimates the national prevalence and number of affected births in the U.S. for 18 major birth defects, over a 3-year span of 1999-2001. Alabama was one of the 11 reporting states used, out of 34 monitored, based on consistency of reports over the last three years of reporting. The most common birth defects were Down

syndrome (12.94 per 10,000 live births) and orofacial defects (cleft lip and palate; 16.82 per 10,000 live births). Two cardiovascular and one gastrointestinal defect were also common. CDC. Improved national prevalence estimates for 18 selected major birth defects – United States, 1999-2001. *MMWR* 2006 Jan;54(51 & 52):1301-05.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5451a2.htm>

Reviews of Note ...

- Halas CJ. Eszopiclone. *Am J Health-Syst Pharm*. 2006 Jan 1;63(1):41-8.
- Marcy TR, Ripley. Aldosterone antagonists in the treatment of heart failure. *Am J Health-Syst Pharm*. 2006 Jan 1;63(1):49-58.
- Berry J. Are all aromatase inhibitors the same? A review of controlled clinical trials in breast cancer. *Clin Ther* 2005 Nov;27(11):1671-84.
- Gilkin RJ Jr. The spectrum of irritable bowel syndrome: A clinical review. *Clin Ther* 2005 Nov;27(11):1696-1709.
- Dale KM, Coleman CI, Henyan NN, Kluger J, White CM. Statins and cancer risk: A meta-analysis. *JAMA* 2006 Jan 4;295(1):74-80.
- van de Beek D, Gans J, Tunkel AR, Wijdicks EFM. Community-acquired bacterial meningitis in adults. *N Engl J Med* 2006 Jan 5;354(1):44-53.
- CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: Immunization of infants, children, and adolescents. *MMWR* 2005 Dec 23;54(RR-16):1-33.
- Montanaro A, ed. Allergy. *Med Clin N Am* 2006 Jan;90(1):1-273. [12 articles on topics such as asthma, anaphylaxis, atopic dermatitis, insect sting and drug hypersensitivity.]

FROM THE LAY LITERATURE about medicine ...



Superfluous research ... A *Washington Post* article has called into question the conducting of multiple clinical trials to test a drug or procedure. They base the story on two studies, one looking at the use of aprotinin to reduce bleeding during heart surgery and the other examining the desirability of putting babies to sleep on their backs, to prevent SIDS. While conceding that scientific trials must be demonstrated reproducible, the authors ask the question, how much is enough? In both of these cases, via meta-analysis, effectiveness was conclusively demonstrated, but additional trials continued for many more years. It was also mentioned that each trial published cited only about 1/5th of the available studies on the topic (poor drug literature searching skills!). The travesty is the number of patients subjected to less than optimal therapy for apparently no good reason.

Brown D. Superfluous medical studies called into question. *Washington Post* 2006 Jan 2; p. A06.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/01/01/AR2006010100749.html?referrer=email>



Diabetes Epidemic ... that is what this article is calling this health crisis. From the *New York Times*, a long story about a variety of patients in the city, that may serve as a microcosm of the U.S. It brings a lot of data together with descriptive patient presentations and gives a real human face to the ravages of this disease.

Kleinfield NR. Bad blood: Diabetes and its awful toll quietly emerge as a crisis. *New York Times.com* 2006 Jan 9.

<http://www.nytimes.com/2006/01/09/nyregion/nyregionspecial5/09diabetes.html?pagewanted=1>

Pill regimens complicated ... Short article emphasizing a typical patient need for help in remembering to take their medication. Think about it ... how many times have you failed to follow dosing instructions precisely, even for a short course of antibiotics? This is compounded, particularly for seniors by the number of dose forms, doses per day, various dose forms (tablets, capsules, patches, inhalers, drops, etc). The article also offers interesting facts and figures.

Students and Pharmacists: Another great area for intervention in PPE and in general practice!

Painter K. Pill regimens test patients. *USA Today* 2006 Jan 9.

http://www.usatoday.com/news/health/2006-01-08-pill-regimens_x.htm



Conflict of interest and big money ... again ... this time it's the surgeon's turn.

Apparently researchers and authors of two articles published in the *Journal of Thoracic and Cardiovascular Surgery* failed to disclose financial ties to an equipment manufacturer. The articles were reporting on the use of a product to treat atrial fibrillation, manufactured by AtriCure, Inc. The publisher is considering sanctions of barring the authors, and any others from their institution, from publishing in their journal for a period of time. It is a severe sanction, as such go. Some of the data itself was also challenged.

Armstrong D. Surgery journal threatens ban for authors' hidden conflicts. *Wall Street Journal* 2005 Dec 28; p. B1.



The last "dose" ...

National Birth Defects Prevention Month and National Folic Acid Awareness Week

January is National Birth Defects Prevention Month, and January 9 to 15 is National Folic Acid Awareness Week. Health-care professionals are encouraged to help women of childbearing age practice healthy preconceptional and prenatal behaviors, including taking multivitamins containing folic acid, managing chronic medical conditions, having regular medical examinations, and avoiding alcohol, tobacco, and illicit drugs.

Taking folic acid before and during early pregnancy can prevent serious birth defects of the spine and brain (i.e., neural tube defects). The rates of such birth defects declined 26% after folic acid was first added to cereal-grain products in 1998 via federal mandate.

Information on Birth Defects Prevention Month is available from the March of Dimes (<http://www.marchofdimes.com>) and the National Birth Defects Prevention Network (<http://www.nbdpn.org>). Information on National Folic Acid Awareness Week is available from the National Council on Folic Acid (<http://www.folicacidinfo.org>). For more information: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5451a1.htm>

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

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