

AU InforMed

Volume 4 Number 4 (Issue 101)

Wednesday, February 1, 2006



Key Inforbits

- **FOUR** new drugs in the last week!
- Good news/bad news for fish
- Guidelines for interactions with Big Pharma
- World-wide birth defects report
- Where do all of those drugs go ...?
- **Happy Groundhog Day** 🐉

NEW DRUGS, and other related stuff ...

New Drug ... The FDA approved **lubiprostone** (**Amitiza**[™] marketed by Sucampo Pharmaceuticals, Inc. and Takeda Pharmaceuticals America) on January 31, 2006. It is the first drug of its chemical type, for the treatment of chronic constipation of unknown cause in adults. Chronic idiopathic constipation is one of the most common disorders suffered by Americans, affecting women more often than men and also affecting older patients after the age of 65 more frequently. Lubiprostone increases the intestinal fluid secretion, which eases the passage of stool and alleviates symptoms associated with chronic idiopathic constipation. The most common adverse events include headache, nausea, diarrhea, abdominal pain, and distension. Lubiprostone should be taken twice daily with food; use should be periodically reassessed.

FDA. FDA approves new prescription drug for adults for treatment of chronic "idiopathic" constipation. *FDA News* 2006 Jan 31; P06-14.

<http://www.fda.gov/bbs/topics/news/2006/NEW01305.html> (FDA News)

<http://www.amitiza.com/> (Company web site)

New Drug ... A new drug was approved by the FDA on January 27, 2006. It is **ranolazine** extended release tablets (**Ranexa**[™] by CV Therapeutics) and is approved for treatment of chronic angina. Ranolazine prolongs the QT interval and is a second-line agent. It should be used in combination with other antianginals. Its mechanism is unknown but effects do not depend on reduction of heart rate or blood pressure. Dosing is 500mg or 1000mg twice daily. The drug is expected to be available at the end of March.

www.cvt.com (Company web site with press release and package labeling)

New Drug ... The FDA approved **sunitinib** (**Sutent**[®] by Pfizer Labs), a targeted anti-cancer treatment for patients with gastrointestinal stromal tumors (GIST), a rare stomach cancer, and advanced kidney cancer, on January 26, 2006. Sunitinib received a priority review and was approved in less than six months. It is a tyrosine kinase inhibitor working through multiple targets to deprive the tumor cells of the blood and nutrients needed to grow. According to the American Cancer Society, about 32,000 new cases of advanced kidney cancer and 5,000 cases of GIST are diagnosed each year. More than 1700 patients are being treated with sunitinib through an expanded access program from Pfizer Labs. According to the manufacturer, the drug will be available on February 3, 2006.

FDA. FDA Approves New Treatment for Gastrointestinal and Kidney Cancer. *FDA News* 2006 Jan 26; P06-11.

<http://www.fda.gov/bbs/topics/news/2006/NEW01302.html>

http://www.sutent.com/sutent/Active/content/Sutent_P1_Home.jsp (Labeling information)

New Drug ... FDA has approved **Exubera**[®], an inhaled powder form of recombinant human insulin (rDNA) for the treatment of adult patients with type 1 and type 2 diabetes, manufactured by Pfizer. It is the first new insulin delivery method introduced since the discovery of insulin in the 1920s. Exubera[®] is inhaled into the lungs through the mouth using a special inhaler. Its action most closely resembles regular insulin. Other than side effects associated with insulin, cough, shortness of breath, sore throat, and dry mouth are common. In addition, Exubera[®] is not to be used if the patient smokes or recently quit smoking (within the last 6 months) or in patients with asthma, bronchitis, or emphysema. Baseline lung function tests are recommended before beginning treatment and should be repeated every 6 to 12 months thereafter.

FDA. FDA approves first ever inhaled insulin combination product for treatment of diabetes. *FDA News* 2006 Jan 27; P06-13.

<http://www.fda.gov/bbs/topics/news/2006/NEW01304.html>

MedWatch ... Bristol-Myers Squibb announced revisions to the Warnings and Adverse Reactions sections of the prescribing information to describe cutaneous vasculitic toxicities, including vasculitic ulcerations and gangrene, in patients with myeloproliferative disorders treated with **hydroxyurea**, most often reported in patients with a history of or currently receiving interferon therapy. The Precautions and Dosing and Administration sections have been revised to provide updated information on the safe handling of these products. The proposed changes are highlighted in the following "Dear Healthcare Provider" letters issued January 2006 by Bristol-Myers Squibb; specific wording of these additions and revisions to the labeling is pending FDA review and approval.

Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare Professional letters, at:

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

FROM THE MEDICAL LITERATURE ...



Forget the fish, gimme a steak ... Perhaps an overreaction, but a recent systematic review of 38 studies involving 20 cohorts from seven countries, for 11 different cancers showed that omega-3 fatty acid consumption did not change the risk of developing cancer. The populations were heterogeneous and did not allow for pooling of data. According to the data presented, it wasn't even very close.

MacLean CH, Newberry SJ, Mojica WA, Khanna P, Issa AM, Suttorp MJ, et al. Effects of omega-3 fatty acids on cancer risk: A systematic review. *JAMA* 2006 Jan 25;295(4):403-15.



Big Pharma takes another one on the chin ... A group of medical academicians has offered a proposal to reduce the influence of the pharmaceutical industry on physician prescribing. They present a compelling argument for academic medical centers to:

- Eliminate gifts of all kinds, including meals, travel, time, etc. (zero dollar amount)
- Eliminate drug samples, and replace with a voucher system for low income patients
- Eliminate all health professionals from formulary committees that have financial relationships with the pharmaceutical industry
- Eliminate direct financial support of continuing education; rather funnel funds through a central office of the academic medical center, to be disbursed.
- Eliminate funds for meeting/convention travel; rather funnel funds through a central office of the academic medical center, to be disbursed.

- Prohibit faculty from serving on speaker's bureau's and publishing articles and editorials that have been ghostwritten by a sponsoring company.
- Consulting and research contracts should be specific, with stated deliverables, rather than open-ended grants. General grants are acceptable, but again controlled through a central office in the academic medical center, to distance faculty from the funding source.

Be sure and let me know how this works out!

Brennan TA, Rothman DJ, Blank L, Blumenthal D, Chimonas SC, Cohen JJ, et al. Health industry practices that create conflicts of interest: A policy proposal for academic medical centers. *JAMA* 2006 Jan 25;295(4):429-33.



Followed by a 1-2 punch ... An individual academic medical center (Yale Medical Group) has also recently published guidelines for interactions between their physicians and the pharmaceutical industry. Theirs follow a very similar pattern as those proposed in the *JAMA* article above, but appear to be independently conceived. This article also compares their guidelines to other national guidelines on the same topic. These guidelines are more detailed and make more specific allowances for circumstances. These were put together with collaboration with representatives of the pharmaceutical industry.

Coleman DL, Kazdin AE, Miller LA, Morrow JS, Udelsman R. Guidelines for interactions between clinical faculty and the pharmaceutical industry: One medical school's approach. *Acad Med* 2006 Feb;81(2):154-160.

Birth Defects report ... A 98-page report was released January 30, 2006, by the March of Dimes that describes the rate of birth defects world-wide. The report gives a lot of data. World-wide the rate of birth defects is about 6%; it rises to 7% to 8% in Africa and the Middle East, and is lowest in Europe, Russian Federation and the U.S. at about 4% to 4.8%. The March of Dimes believes this rate could be dramatically reduced by better diets in developing countries and medical screenings.

Christianson A, Howson CP, Modell B. *March of Dimes. Global report on birth defects: The hidden toll of dying and disabled children*. White Plains, NY: March of Dimes Birth Defects Foundation, 2006.

http://www.marchofdimes.com/professionals/871_18587.asp

Reviews of Note ...

- Barrett BJ, Parfrey PS. Preventing nephropathy induced by contrast medium. *N Engl J Med*. 2006 Jan 26;354(4):379-86.

FROM THE LAY LITERATURE about medicine ...



Career options ... *U.S. News and World Report* has published a list of 16 excellent careers for 2006, eight of which are healthcare related, and of course, pharmacist is one of them. The article provides a brief description of the career choice and also provides links for more information. Another career choice is professor, so a career choice of pharmacy professor would be classified as "most excellent!"

Submitted by R. Lee Evans, Pharm.D.

Nemko M. Career Center: Excellent careers for 2006. *US News & World Report* 2006 Jan 5.

http://www.usnews.com/usnews/biztech/articles/060105/5careers_excellent.htm



It's in the water ... Ever wonder where all of those drugs go after you have ingested (or otherwise administered) them? According to the *LA Times*, into the water supply, along with all

of those old drugs you may have advised to be flushed down the toilet. The good news is, the quantities are miniscule; the bad news is no one knows what the effects might be over many years. Then there is the aquatic life, the effects on them directly or in humans secondarily (think mercury). It is a worldwide problem. A number of examples are given and some of the very few effects we know about.

Cone M. Traces of prescription drugs found in southland aquifers. *Los Angeles Times.com* 2006 Jan 30.

<http://www.latimes.com/news/local/la-me-drugs30jan30,0,5723467.story?coll=la-home-local>

TIMELY TOP TECH TIP ...



Find-a-doc ... There are more Internet sites popping up that aid in finding a physician. This isn't really new, but the specificity is. The intent of these sites is to allow patients to find a physician, sorted by various affinities, based on race, religion, and even sexual orientation. The numbers of referrals will be based on the area searched, but most of them are not "well-stocked" at the moment.

Payne JW. Your Kind of Doctor: Some Web Sites Help Patients Find Physicians of Their Race, Religion or Sexual Sensitivities. Credentials? Well . . . *Washington Post.com* 2006 Jan 31; p. HE01.

[http://www.washingtonpost.com/wp-](http://www.washingtonpost.com/wp-dyn/content/article/2006/01/30/AR2006013001238.html?referrer=email)

[dyn/content/article/2006/01/30/AR2006013001238.html?referrer=email](http://www.washingtonpost.com/wp-dyn/content/article/2006/01/30/AR2006013001238.html?referrer=email)



The last "dose" ...



HAPPY GROUNDHOG DAY!



Why February 2?

The beginning of February, which falls about halfway between the winter solstice and the spring equinox, has long been a significant time of the year in many cultures. Among the Celts, it was the time of the birth of farm animals and the planting of crops; it also marked the date of the Christian festival of *Candlemas* also called the feast of the Purification of the Blessed Virgin.

During the Middle Ages, people believed that animals such as the badger and the bear interrupted their hibernation to appear on this day. If the day was sunny and the animal saw its shadow, six more weeks of winter weather remained. If, however, the day was cloudy, it was a sign that the weather during the following weeks would be mild, leading to an early spring. German immigrants to the U.S. carried the legend with them, and in Pennsylvania the groundhog replaced the badger, and voila!

"Groundhog Day." *Encyclopædia Britannica*. 2006. Encyclopædia Britannica Online. 31 Jan. 2006
<<http://search.eb.com/eb/article-9038219>>.

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