

AU InforMed

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Key Inforbits

- 2 new drugs for blood clots and gout
- New guidelines for chronic pain
- Globalization of drug research-ethical problems
- A master race in development?
- Patient information – too varied?
- Happy Mardi Gras! 

NEW DRUGS, and other related stuff ...

New Drug ... (2/6/2009) The FDA has issued its first approval for a biological product produced by genetically engineered (GE) animals. It is **ATryn[®]** (a recombinant form of human **antithrombin**, also known as ATIII), an anticoagulant used for the prevention of blood clots in patients with a rare disease known as hereditary antithrombin (AT) deficiency (by GTC Biotherapeutics, Inc., Framingham, MA). These patients are at high risk of blood clots during medical interventions, such as surgery, and before, during and after childbirth. ATryn[®] is a therapeutic protein derived from the milk of goats that have been genetically engineered by introducing a segment of DNA into their genes (called a recombinant DNA or rDNA construct) with instructions for the goat to produce human antithrombin in its milk. Antithrombin is a protein that naturally occurs in healthy individual and helps to keep blood from clotting in the veins and arteries. GTC Biotherapeutics, Inc. received approvals from two FDA centers. The Center for Biologics Evaluation and Research (CBER) approved the human biologic based on its safety and efficacy, and the Center for Veterinary Medicine (CVM) approved the rDNA construct in the goats that produce ATryn[®]. Because hereditary AT deficiency occurs in approximately 1 in 5,000 people in the United States, the FDA granted ATryn[®] an orphan drug designation. Hereditary AT deficiency generally is first recognized and diagnosed in teenagers or young adults when they develop clots in their blood vessels, particularly during pregnancy, surgery, or prolonged bed rest.

A summary of the information on which the FDA made its approval decision for the rDNA construct in the goats, and CVM's guidance on the regulation of GE animals containing heritable rDNA constructs are available at <http://www.fda.gov/cvm/GEAnimals.htm>.

<http://www.fda.gov/bbs/topics/NEWS/2009/NEW01952.html> (FDA News, 2/6/2009)

<http://www.gtc-bio.com/products/atryn.html> (Manufacturer Press Release, 2/9/2009)

New Drug ... (2/13/2009) The FDA has approved **Uloric[®]** (**febuxostat** by **Takeda Pharmaceuticals**) 40 mg and 80 mg tablets for the chronic management of hyperuricemia in patients with gout. This once-daily, oral medication is the first new treatment option in more than 40 years for the more than five million patients who have hyperuricemia associated with gout. Uloric[®] is a xanthine oxidase inhibitor that effectively lowers levels of serum uric acid in patients with hyperuricemia associated with gout. The most commonly reported adverse reactions are liver function abnormalities, nausea, joint pain and rash. Uloric[®] is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline.

http://www.ulooric.com/?gclid=CKOim_zi4ZgCFsBinAodkigqcw (Manufacturer package insert and press release)

REMS for Opioids ... (2/9/2009) The FDA has sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a **Risk Evaluation and Mitigation Strategy (REMS)** to ensure that the benefits of the drugs outweigh the risks. The affected opioid drugs include branded and generic products and are formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The FDA has invited those companies that market the affected opioid drugs to a meeting with the agency on March 3 to discuss REMS development. Additional steps will include discussions with other federal agencies and non-government institutions, including patient and consumer advocates, representatives of the pain and addiction treatment communities, other health care professionals, and other interested parties. More information and a list of affected drugs are available at: <http://www.fda.gov/cder/drug/infopage/opioids/default.htm>

MedWatch ... (2/12/2009) The FDA and Roche Laboratories notified healthcare professionals of the introduction of a **CellCept® (mycophenolate mofetil) Medication Guide** to provide important safety information in language that patients can easily comprehend. FDA regulations require a pharmacist to distribute a copy of the Medication Guide to every patient who fills a CellCept® prescription from this point forward. FDA has also required the introduction of a Medication Guide for mycophenolic acid, marketed as Myfortic® by Novartis. Read the complete MedWatch 2009 Safety summary including links to the Dear Healthcare Professional and Dear Pharmacist letters, the new Medication Guide and the current Prescribing Information, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#CellCept>

MedWatch ... (2/19/2009) The FDA issued a Public Health Advisory to notify healthcare professionals of three confirmed, and one possible report of **progressive multifocal leukoencephalopathy (PML), a rare brain infection, in patients using the psoriasis drug Raptiva®** (efalizumab by Genentech and Xoma). In October 2008, the labeling for Raptiva® was changed to highlight, in a Boxed Warning, the risks of life-threatening infections, including PML. In addition, FDA directed Genentech to develop a Risk Evaluation and Mitigation Strategy (REMS), to ensure that patients receive risk information about Raptiva®. The agency will take appropriate steps to ensure that the risks of Raptiva® do not outweigh its benefits, that patients prescribed Raptiva® are clearly informed of the signs and symptoms of PML, and that health care professionals carefully monitor patients for the possible development of PML. Read the MedWatch safety summary, including links to the Public Health Advisory and News Release, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Raptiva>

FROM THE MEDICAL LITERATURE ...

Guidelines for Pain ... The American Pain Society and the American Academy of Pain



Medicine collaborated to provide a systematic review of the literature on chronic opioid therapy for chronic noncancer pain. A multidisciplinary panel then met to review the evidence and provide recommendations. Although generally evidence is limited, the guidelines cover a range of topics including: patient selection, risk stratification, management plans, dosing strategies, prevention/management of opioid adverse effects, breakthrough pain, opioids in pregnancy and various opioid-related policies.

Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, et al, for the American Pain Society – American Academy of Pain Medicine Opioids Guidelines Panel. Opioid treatment guidelines: Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009 Feb;10(2):113-130.

<http://www.jpain.org/article/PIIS1526590008008316/fulltext>

Globalization of clinical trials ... many news services picked up on this recent article that centers on the decade-long trend of pharmaceutical companies conducting more of their clinical research overseas, often in developing countries which has doubled over the decade. Now, approximately 1/3 of trials and more than 1/2 of the sites are located outside of the U.S. The benefits are straightforward: its cheaper. The concerns are not quite (patients or residents of that country the clinical trial results (publication oversight; training and experience of payments and commercialization; and confidentiality concerns. The authors have done a nice job of laying out the concerns and proposed solutions.



faster, less regulatory barriers and therefore as obvious and these include: justice benefit from the research?); transparency of rights and access to trial data); regulatory investigators; IRB training and oversight;

Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, Schulman KA. Ethical and scientific implications of the globalization of clinical research. *N Engl J Med.* 2009 Feb 19;360(8):816-823.

Reviews of Note ...

- Koch HJ, Jürgens TP. Antidepressants in long-term migraine prevention. *Drugs.* 2009;69(1):1-19.
- Murphy AB, Macejko A, Taylor A, Nadler RB. Chronic prostatitis: Management strategies. *Drugs.* 2009;69(1):71-84.
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- Kintzel PE, Chase SL, Thomas W, Vancamp DM, Clements EA. Anticholinergic medications for managing noisy respirations in adult hospice patients. *Am J Health-Syst Pharm.* 2009 Mar 1;66:458-464.
- Schlosser RJ. Epistaxis. *N Engl J Med.* 2009 Feb 19;360(8):784-789.

FROM THE LAY LITERATURE about medicine ...

The Master Race may be coming ... It truly is becoming a 'brave new world.' Scientists have been practicing "pre-implantation genetic diagnosis" or PGD for several years. This is where several eggs are taken from a woman and fertilized. After a few days, the embryo's are tested for genetic markers and up until now with the intent of selecting the embryo without the markers for various genetic diseases and then implanted in the woman. Some clinics in the U.S. (unfettered by regulations) are now offering the same service with the intent of selecting physical characteristics such as gender, hair and eye color. Will it be long until many other traits can be selectively chosen such as intelligence or athletic ability? There are scientists and patients lining up on both sides. Without some sort of regulation the sky is the limit and it will be here soon.

Naik G. A baby, please. Blond, freckles – hold the colic: Laboratory techniques that screen for diseases in embryos are now being offered to create designer children. *Wall Street Journal.* February 12, 2009.

<http://online.wsj.com/article/SB123439771603075099.html?mod=djemHL> [subscription only]

Patient information – highly varied ... Apparently the FDA is fed up! The patient information commonly dispensed with prescriptions is produced primarily by private publishers and the pharmaceutical industry. Approximately 10 years ago, the FDA was poised to mandate requirements for this information, but the publishers and industry persuaded Congress to block the move with promises to exceed the FDA expectations for quality and usefulness within a time frame. Time is up and the FDA is not impressed. Based on a study conducted for the FDA, the information is highly variable (pharmacies can also edit the information) and in 6% of pharmacies, no information was given. We will see what all that money will buy us this time.



Young A. Pharmacies' data on drugs often varies. Atlanta Journal-Constitution, February 22, 2009.

<http://www.ajc.com/services/content/printedition/2009/02/22/spotlight02223dot.html>

AUBURN HSOP FACULTY and STUDENTS in the literature ...

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NEW RESOURCES in the DILRC ...

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- Fincham JE. E-Prescribing: The Electronic Transformation of Medicine. Sudbury, MA: Jones and Bartlett Publishers, 2009.



The last "dose" ...

It [Mardi Gras] is a thing that could hardly exist in the practical North ... For the soul of it is the romantic, not the funny and the grotesque. Take away the romantic mysteries, the kings and knights and big-sounding titles, and Mardi Gras would die, down there in the South.



~Life on the Mississippi (Harper & Brothers, 1896) by Mark Twain

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