



## Key Inforbits

- Zonisamide, metoclopramide, MRI burns ...
- Guidelines for psoriasis, rheumatic fever
- Diets, it doesn't matter
- Conservative prescribing principles
- Stairway to fitness
- Sometimes its integrity that's the problem

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

**New Dose Indication** ... (2/26/2009) The FDA has approved **Synvisc-One™** (hylan G-F 20 by Genzyme Corp.), for the relief of pain associated with osteoarthritis (OA) of the knee. Synvisc-One™ is administered through a single intra-articular injection. It is an alternative treatment regimen to Genzyme's Synvisc® (hylan G-F 20), a three-injection viscosupplement approved in the U.S. in 1997. Synvisc-One™ contains the same material and total treatment volume as Synvisc® but provides the 6 mL of hylan G-F 20 in a single injection. Viscosupplementation is a procedure in which hyaluronic acid or a derivative such as hylan G-F 20 is injected into the knee joint to replace synovial fluid that typically becomes degraded in patients with osteoarthritis. In synovial fluid, hyaluronic acid relieves pain and improves the knee's shock absorbing abilities.

<http://www.genzyme.com/corp/media/GENZ%20PR-022609.asp#TopOfPage> [Mfr Press Release]

**Medical Food** ... (3/2/2009) The FDA has approved **Axona™** (by Accera, Inc), a medical food (proprietary formulation of caprylic triglyceride) for treatment of mild-to-moderate Alzheimer's disease (AD). The first-in-class medical food, dispensed by prescription, targets the metabolic deficiencies and imbalances associated with AD by providing an alternative energy source for brain cells. In a double-blind, randomized, placebo-controlled study of 152 patients with AD, those taking Axona™ demonstrated significant improvements in cognitive function by day 45. These patients also maintained a slight improvement from baseline after 90 days of daily Axona™ administration, whereas the placebo group showed a decline. The powder formulation is mixed with water and consumed at breakfast; it is complementary to other AD therapies.

<http://www.accelerapharma.com/2009/news30.html> (Manufacturer web site)

**MedWatch** ... (2/23/2009) The FDA notified healthcare professionals that updated clinical data has determined that treatment with **zonisamide (Zonegran®)**, indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy, **can cause metabolic acidosis** in some patients. Patients with predisposing conditions or therapies may be at greater risk for developing metabolic acidosis; the risk of zonisamide-induced metabolic acidosis appears to be more frequent and severe in younger patients. FDA recommends that healthcare professionals measure serum bicarbonate before starting treatment and periodically during treatment with zonisamide, even in the absence of symptoms and is working with the makers of zonisamide to revise the product labeling to reflect this new information. The notification includes recommendations for healthcare providers, information for patients, and a data summary.

Read the MedWatch 2009 safety summary, including a link to the "Information for Healthcare Professionals" sheet, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Zonisamide>

**MedWatch** ... (2/27/2009) The FDA notified healthcare professionals that manufacturers of metoclopramide, a drug used to treat gastrointestinal disorders, must add a boxed warning to the drug labels about the risk of its long-term or high-dose use. **Chronic use of metoclopramide has been linked to tardive dyskinesia**, which may include involuntary and repetitive movements of the body, even after the drugs are no longer taken. These symptoms are rarely reversible and there is no known treatment. Names of metoclopramide-containing products include Reglan Tablets, Reglan Oral Disintegrating Tablets, Metoclopramide Oral Solution, and Reglan Injection. Manufacturers will be required to implement a risk evaluation and mitigation strategy [REMS] to ensure patients receive a medication guide that discusses this risk. Current product labeling warns of the risk of tardive dyskinesia with chronic metoclopramide treatment. Read the MedWatch 2009 safety summary, including a link to the FDA News Release, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Metoclopramide>

**MedWatch** ... (3/5/2009) The FDA announced that certain **transdermal patches** containing aluminum or other metals in their backing **can overheat during an MRI scan** and cause skin burns in the immediate area of the patch. The FDA is reviewing the labeling and composition of all medicated patches to ensure that those made with materials containing metal provide a warning about the risk of burns to patients who wear the patches during an MRI scan. Healthcare professionals referring patients for an MRI scan should identify patients who are wearing a patch before the patients have the MRI scan and should advise these patients about removing and disposing of the patch before the MRI scan, and replacing the patch after the MRI scan. Read the MedWatch safety summary, including a link to the FDA Public Health Advisory, at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Transdermal>

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

**Guidelines for topical treatment of psoriasis** ... The American Academy of Dermatology has released their third of a six-part guideline series on psoriasis. This section deals with the  treatment of psoriasis with topical therapies. The majority of patients can be managed with topical therapy which have high efficacy-to-safety ratios. Single entity and combination therapies are discussed along with their efficacy and safety and recommendations. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 10.1016/j.jaad.2008.12.032. [http://www.aad.org/research/guidelines/\\_doc/Pso3Topicals.pdf](http://www.aad.org/research/guidelines/_doc/Pso3Topicals.pdf)

**Guidelines for Prevention of Rheumatic Fever** ... This is a scientific statement from the American Heart Association and endorsed by the American Academy of Pediatrics that updates a 1995 statement concerning prevention of rheumatic fever and diagnosis and treatment of acute streptococcal pharyngitis. The statement emphasizes the importance of identification and adequate treatment of group A  $\beta$ -hemolytic streptococcal tonsillopharyngitis as well as that penicillin is the usual antibiotic of choice due to effectiveness, lack of documented resistance and cost-effectiveness.

Gerber MA, Baltimore RS, Eaton CB, Gewitz M, Rowley AH, Shulman ST, Taubert KA. Prevention of Rheumatic Fever and Diagnosis and Treatment of Acute Streptococcal Pharyngitis: A Scientific Statement From the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee of the Council on Cardiovascular Disease in the Young, the Interdisciplinary Council on Functional Genomics and Translational Biology, and the Interdisciplinary Council on Quality of Care and Outcomes Research. Circulation. 2009;119:000-000. DOI: 10.1161/CIRCULATIONAHA.109.191959 <http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.109.191959v1>

**It doesn't matter** ... what diet you follow, they all work about the same, at least that is a general conclusion from a recent (well publicized) study that compared four diets that varied the amount of fat, protein and carbohydrate, and monitored the 811 adults over 2 years. The investigators also felt that behavioral characteristics played a big role. After the initial weight loss, over the two years, weight began to creep back but subjects still weighed less at the end of the two years. An accompanying editorial also emphasized the behavioral aspects and cited two community projects in France that successfully attacked childhood obesity. May be it does take a village ...



Sacks FM, Bray GA, Carey VJ, Smith SR, Ryan DH, Anton SD, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. *N Engl J Med.* 2009 Feb 26;360(9):859-873.

Katan MB. Weight-loss diets for the prevention and treatment of obesity. *N Engl J Med.* 2009 Feb 26;360(9):923.

**But it may not be your fault** ... if you are overweight, it may be due to the cookbook conspiracy! Enterprising investigators evaluated a cookbook, *The Joy of Cooking*, over seven editions since 1936. There were 18 recipes that were published in all editions over the 70 years. Total caloric content for 14 of 18 recipes increased; mean caloric content increased in 17 of 18 recipes by 43.7%. These increases are due to both the change to higher calorie ingredients and increases in serving size. This coupled with the documented increases in serving sizes in “away-from-home” sources, and what chance do we have?!?



Wansink B, Payne CR. The Joy of Cooking to much: 70 years of calorie increases in classic recipes. *Ann Intern Med.* 2009 Feb 17;150(4):291.

**Promoting Conservative Prescribing** ... this may be worth sharing with the local doc's. Two well-known physicians involved in patient safety have offered “25 Principles of Conservative Prescribing” based on six broad areas: Think beyond drugs; more strategic prescribing; heightened adverse effects vigilance; Caution and skepticism regarding new drugs; shared agenda with patients; and weigh long-term broader impacts. They may be onto something!

Schiff GD, Galanter WL. Promoting more conservative prescribing. *JAMA.* 2009 Feb 25;301(8):865-867.

### Reviews of Note ...

- Lyseng-Williamson KA, Siddiqui MAA. Pregabalin: A review of its use in fibromyalgia. *Drugs.* 2008;68(15):2205-2223.
- Wasserbauer N, Ballow M. Atopic dermatitis. *Am J Med.* 2009 Feb;122(2):121-125.
- Medarov BI. Milk-alkali syndrome. *Mayo Clin Proc.* 2009 Mar;84(3):261-267.
- Schnyder B, Pichler WJ. Mechanisms of drug-induced allergy. *Mayo Clin Proc.* 2009 Mar;84(3):268-272.
- Sampathkumar P, Drage LA, Martin DP. Herpes zoster (shingles) and postherpetic neuralgia. *Mayo Clin Proc.* 2009 Mar;84(3):274-280.
- Farooq MU, Bhatt A, Majid A, Gupta R, Khasnis A, Kassab MY. Levetiracetam for managing neurologic and psychiatric disorders. *Am J Health-Syst Pharm.* 2009 Mar 15;66:541-561.
- Fanta CH. Asthma. *N Engl J Med.* 2009 Mar 5;360(10):1002-1014.

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

**It can only go up** ... For those of you on a budget but would like to start a workout program, here is an option, and it is free. Stair-climbing! A surge of interest was created with the recent race to the top of the Empire State Building. But it makes a lot of sense, particularly if you find

using some of those gym machines (stair-steppers, treadmills) as an expensive substitute for something readily available (stairs, sidewalks). It's estimated that the calorie burn per minute per person is 5 calories for a 120 lbs person; 7 for 150 lbs person; and 9 for 180 lbs. Running up stairs increases the calorie consumption and increases cardiovascular benefit. In addition to making sure you are physically able to do this (check with your physician), another tip is to walk up and take the elevator down – walking down stairs increases the pounding on your knees 6-7 times.



Robbins L. Great workout, forget the view. New York Times. February 19, 2009.

<http://www.nytimes.com/2009/02/19/health/nutrition/19fitness.html?ref=health>

**Another form of bias difficult to control ...** A top anesthesiologist has allegedly faked at least twenty-one (yes, 21) medical studies on a variety of analgesics including several NSAIDs. These were published in several anesthesiology journals over 12 years (since 1996). Most of these articles have been retracted by the journals. The discrepancies apparently surfaced after a routine audit by the hospital employer of the physician. In addition to the serious nature of these allegations on the physician, the hospital, funding sources (including Pfizer), and the studies, these studies have also formed the basis of newer theories and methods of pain control which must now be reconsidered.

Winstein KJ, Armstrong D. Top pain scientist fabricated data in studies, hospital says. Wall Street Journal. March 11, 2009.

<http://online.wsj.com/article/SB123672510903888207.html?mod=djemHL> (subscription only)

### **NEW RESOURCES in the DILRC ...**

- Davis NM. Medical Abbreviations: 30,000 Conveniences at the Expense of Communication and Safety. 14<sup>th</sup> ed. Warminster, PA: Neil Davis Associates, 2009.
- Posey LM. Pharmacy: An Introduction to the Profession. 2<sup>nd</sup> ed. Washington, DC: American Pharmacists Association, 2009.



**The last “dose” ...**

May your blessings outnumber  
The shamrocks that grow,  
And may trouble avoid you  
Wherever you go.  
~Irish Blessing



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