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Key Inforbits

- Major study of pharmacist intervention in HF
- Prescriber profiling profiled, in the U.S.
- May is Stroke Prevention Month
- Cheese is becoming popular
- Psychiatrists are not to be outdone
- **Elephant Pharmacy** is a new model

NEW DRUGS, and other related stuff ...

MedWatch ... (5/2/2007) The FDA notified healthcare professionals that the Agency proposed that makers of **all antidepressant medications update the existing black box warning** on the prescribing information for their products to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment. The proposed labeling changes also state that scientific data did not show this increased risk in adults older than 24 years of age and that adults 65 years of age and older taking antidepressants have a decreased risk of suicidality. The proposed updates apply to the entire category of antidepressants. Individuals currently taking prescribed antidepressant medications should not stop taking them and should notify their healthcare professional if they have concerns. See the FDA press release for the list of products affected by the proposed antidepressant product labeling changes.

Read the complete MedWatch 2007 Safety summary, including a link to the FDA Press Release and Antidepressant Information Page regarding this issue at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Antidepressant>

MedWatch ... (5/10/2007) The FDA informed consumers and healthcare professionals regarding the dangers associated with the purchase or use of **True Man or Energy Max products** promoted and sold as dietary supplements throughout the United States. Both products, promoted as sexual enhancement products and as treatment for erectile dysfunction (ED), are illegal drug products that **contain potentially harmful, undeclared ingredients**. The undeclared ingredients may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Both products contain either a thione analog of sildenafil, the active ingredient of Viagra, or a piperadino analog of vardenafil, the active ingredient in Levitra. Both Viagra and Levitra are FDA approved products for the treatment of ED. The FDA has not approved True Man and Energy Max, therefore, the safety and effectiveness of these products are unknown. Consumers should discontinue use of these products and consult their healthcare professional about approved treatments for ED.

Read the complete 2007 Safety summary, including a link to the FDA News Release regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#TrueMan>

MedWatch ... (5/10/2007) The FDA informed healthcare professionals of criminal charges and civil liabilities brought against Purdue Frederick in connection with several **illegal schemes to promote, market and sell OxyContin**, a powerful prescription pain reliever that the company

produces. The manufacturer's sales force was trained to make false claims about the product to healthcare professionals, thereby, misbranding OxyContin by illegally promoting the drug as being less addictive, less subject to abuse, and less likely to cause tolerance and withdrawal than other pain medications. These practices falsely promote the product and may cause health risks for consumers.

Read the complete 2007 Safety summary, including a link to the FDA Press Release regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#OxyContin>

MedWatch ... (5/17/2007) NBTY and the FDA informed consumers and healthcare professionals of a **nationwide recall of 3 lots of Shark Cartilage Capsules** the company manufactured in 2004 and distributed to consumers through mail and internet orders, and retail stores throughout the United States. There was possible contamination with Salmonella that can cause serious or fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons often experience fever, diarrhea, nausea, vomiting and abdominal pain. Rarely, infection with Salmonella can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections, endocarditis and arthritis. Customers can return the product back to the place of purchase for a full refund. Read the press release for specific names and lot numbers of the recalled product.

Read the complete 2007 Safety Summary, including a link to the Manufacturer's Press Release regarding this issue at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#NBTY>

FROM THE MEDICAL LITERATURE ...

Rosiglitazone and cardiovascular risk ... early release ... A meta-analysis of 42 trials was released today, May 21, 2007 by the New England Journal of Medicine. It concluded that rosiglitazone is associated with an increased risk of myocardial infarction (Odds Ratio of 1.43 [95% CI, 1.03 to 1.98; P=0.03]) and a possible increased risk of death from cardiovascular causes (Odds Ratio of 1.64 [95% CI, 0.98 to 2.74; P=0.06]). An accompanying editorial lends some assistance in the significance of this study. Both are available at www.nejm.org and will be published in the June 14 issue.

Nissen SE, Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes. *N Engl J Med.* 2007 May 21;356:10.1056/NEJMoa072761.

Psaty BM, Furberg CD. Rosiglitazone and cardiovascular risk. *N Engl J Med.* 2007 May 21;356:10.1056/NEJMe078099.

Pharmacist intervention in HF ... Patients with heart failure (n=312) were divided into the usual care group (n=192) and the intervention group (n=122). The interventions consisted of a pharmacist providing an extensive medication history, patient assessment, and patient counseling with specific, tested protocols. Measurements of medication adherence (electronic prescription monitors) and disease exacerbations (primary outcomes) and several secondary outcomes including total direct costs. Patients received the intervention for 9 months with a 3 month follow up. Results showed that pharmacist interventions improved patient adherence, but this dropped off in the 3 month follow up phase. There were fewer emergency department visits and the overall 1 year cost savings averaged \$2960. The paper provides extensive detail on the data collection and endpoints.



Murray MD, Young J, Hoke S, Tu W, Weiner M, Morrow D, et al. Pharmacist intervention to improve medication adherence in heart failure: A randomized trial. *Ann Intern Med.* 2007 May 15;146(10):714-725.

Prescriber profiling ... and physician collusion ... An informative article on the history of prescriber profiling, that is, tracking a physician's record of prescription writing, for purposes of pharmaceutical marketing. Recent attention has been paid to it, but its history dates back to the 1940's and really took hold in the 1950's and 1960's. Interestingly, a pharmacist was one of the first to develop a commercial database for such activity, Raymond Gosselin. However, physicians have been their own worst enemy in this case, as individuals as well as organizations (eg, the AMA) have actively participated in data collection, purely for their own financial benefit, and directly for the marketing and sales benefit of the pharmaceutical industry. Legislatures are now beginning to pass remedies for selling physician data. It would seem a more grass-roots start is more appropriate.



Greene JA. Pharmaceutical marketing research and the prescribing physician. *Ann Intern Med.* 2007 May 15;146(10):742-748.

Grande D. Prescriber profiling: Time to call it quits (editorial). *Ann Intern Med.* 2007 May 15;146(10):751-752.

Prescriber favors ... and as a balance, this article describes a busy, overworked private practice physician who happily sees pharmaceutical representatives, accepts their free lunches and box seats to the baseball game. But, this schmoozing is offset by the free samples of the latest drug this physician receives and in turn provides some relief for a less-than-well-off patient. The implication is this patient would receive no relief if it weren't for the free samples ...



Dudley S. The gifts that keep on giving: As a doctor, he takes the free lunches and free pens. In turn, he gives out free samples -- and hope. *Los Angeles Times.* 2007 May 14. <http://www.latimes.com/features/health/la-he-files14may14,1,4624458.story?coll=la-headlines-health>

May is National Stroke Awareness Month ... Stroke is the third leading cause of death in the U.S. and contributes to extensive health care expenditures. They are highest in the southeast U.S. and Alabama is among the highest in the nation (but not as high as Mississippi). This report breaks down the incidence of stroke by age, gender, race/ethnicity, geographic region and education level. It gives a good picture of what health care professionals are up against.

CDC. Prevalence of stroke – United States, 2005. *MMWR.* 2007 May 18;56(19):469-474.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5619a2.htm>

Reviews of Note ...

- Noel JM. ASHP therapeutic position statement on the use of second-generation antipsychotic medications in the treatment of adults with psychotic disorders. *Am J Health-Syst Pharm.* 2007 Apr 15;64:863-876.
- Nayak A, Langdon RB. Montelukast in the treatment of allergic rhinitis: An evidence-based review. *Drugs.* 2007;67(6):887-901.
- Cvetković RS, Plosker GL. Exenatide: A review of its use in patients with type 2 diabetes mellitus (as an adjunct to metformin and/or a sulfonylurea. *Drugs.* 2007;67(6):935-954.
- Abramowicz M, ed. Choice of antibacterial drugs. *Treatment Guidelines Med Lett.* 2007 May;5(57):33-51.

FROM THE LAY LITERATURE about medicine ...

Vocabulary ... Cheese ... Unfortunately, yet another new combination for drug abuse.



“Cheese” is a combination of black tar heroin and “cold medicine” that has been ground up and is snorted. The name is derived from the appearance of the mixture, resembling parmesan cheese. It is sold in small plastic bags; the amount of heroin is

usually about 3%. It is also relatively cheap, about \$2 a bag. The worst part is that it seems to be most popular in young teens, some as young as 11 to 12 years old. Deaths in Dallas, TX have reached 21, and officials are hoping it use doesn't spread. The problem is overdose of heroin for uninitiated users when they obtain a mixture that may be 9% to 10% heroin.

Skip C, Campo-Flores A. Stopping a kid killer. *Newsweek*. 2007 May 21;149(21):40.

<http://www.msnbc.msn.com/id/18628591/site/newsweek/>

Physicians and big Pharma ... an old and now more specific story ... A recent investigative article from the *New York Times* looking into the influence of the pharmaceutical industry on psychiatry. Using data from Minnesota, the only state requiring public reports of all drug company marketing payments to physicians, several examples are cited of psychiatrists taking substantial amounts of money in exchange for lectures on bipolar disorders. Coincidentally, prescriptions for the newer atypical antipsychotics rose several fold over the last few years, and particularly use in children, where precious little data exist. The prescribers deny any undue influence on their clinical judgments.

Harris G, Carey B, Roberts J. Psychiatrists, children and drug industry's role. *New York Times*. 2007 May 10.

<http://www.nytimes.com/2007/05/10/health/10psyche.html?ref=health>

Elephant Pharmacy ... For those of you who own your own pharmacy, or those of you considering the move, here is a story of one such practitioner. It gives new meaning to the phrase of "full service pharmacy." In addition to standard prescriptions and OTC selection, the pharmacy offers veterinary medicine and an extensive array of alternative/complementary therapies. This includes yoga, ayurvedic medicine, several "philosophies" of herbal medicine, organic foods, solar energy alternatives and much more. In addition, it has the backing of several big investors, including CVS Pharmacy. It is located in (where else) Berkley, CA and they report steady and increasing profits.



http://www.nytimes.com/2007/05/16/business/smallbusiness/16elephant.html?_r=1&oref=slogin

AUBURN HSOP FACULTY in the literature ...

- Duncan-Hewitt W, Jungnickel P, Evans RL. Development of an office of teaching, learning and assessment in a pharmacy school. *Am J Pharm Educ*. 2007;71(2):Article 35.



The last "dose" ...

"Physician [and others], heal thyself."
-- The Gospel According to Saint Luke, 4:23

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