

AU InforMed

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Key Inforbits

- More evidence – chocolate is good for you
- Talk is cheap – as least for diet and weight loss
- But, new options – Lipo-dissolve
- Pharmaceutical influence again
- Drug abuse is serious, including local
- Poisons and medicines?

NEW DRUGS, and other related stuff ...

New Dose Form ... (7/6/2007) Rivastigmine transdermal system (Exelon[®] Patch by Novartis) has been approved by the FDA. It delivers rivastigmine for treatment of mild to moderate Alzheimer's disease through a skin patch instead of an oral capsule. It is the first and only transdermal treatment for this degenerative condition. Exelon[®] Patch maintains steady drug serum levels, improving tolerability and allowing a higher proportion of patients to receive therapeutic doses compared to the capsule form of the medication. It is applied to the back, chest or upper arm, and it provides smooth and continuous delivery of medication through the skin over 24 hours. GI side effects are commonly seen with this class of drugs called cholinesterase inhibitors and the Exelon[®] Patch reduces these side effects, with three times fewer reports of nausea and vomiting than with the capsule form of the drug.

Exelon[®] Patch is expected to be available in US pharmacies soon.

http://www.exelonpatch.com/index.jsp?usertrack.filter_applied=true&NovaId=1043275422871
[Package Labeling]

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails>
[Drugs@FDA]

MedWatch – (7/3/2007) Genentech and the FDA informed healthcare professionals and asthmatic patients that the **prescribing information for Xolair[®] (omalizumab) was revised** to include a new Boxed Warning and updated Warnings, Precautions, and Adverse Reactions sections that address the risk of anaphylaxis (the onset of action can be delayed for 24 hours or more) when taking this medication. In addition, a new Medication Guide was developed and will be provided to patients when a prescription for Xolair[®] is filled or refilled at the pharmacy. Due to the risk of anaphylaxis, Xolair[®] should only be administered to patients in a healthcare setting under direct medical supervision. Patients should be observed for an appropriate period of time following each Xolair[®] injection. Read the complete MedWatch 2007 Safety Summary, including a link to the FDA Healthcare Professional Information Sheet, and the manufacturer's Prescribing Information, and Medication Guide for Xolair[®] regarding this issue at:

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

MedWatch ... (7/5/2007) Merck and the FDA informed healthcare professionals that 3 lots of **Invanz[®] (ertapenem)** (0803930, 0803940, and 0803950), a product indicated for the treatment of patients with moderate to severe infections caused by susceptible isolates of the designated microorganisms, were **recalled**. The product was recalled because of two incidents of finding

broken glass pieces in the reconstituted solution for injection. Healthcare professionals are advised to immediately stop dispensing all products from the three lots specified above. Read the complete MedWatch 2007 Safety Summary including a link to the manufacturer's Dear Healthcare Professional Letter at:

<http://internet-dev/medwatch/safety/2007/safety07.htm#Invanz>

MedWatch ... (7/5/2007) Roche and the FDA informed healthcare professionals of revisions to the Contraindications, Warnings, Precautions, Adverse Reactions, and Dosage and Administration sections of the prescribing information for Rocephin® (ceftriaxone) for Injection. The revisions are based on new information that describes the potential risk associated with **concomitant use of Rocephin® with calcium or calcium containing solutions or products**. Cases of fatal reactions with calcium-ceftriaxone precipitates in the lungs and kidneys in both term and premature neonates were reported. Hyperbilirubinemic neonates, especially prematures, should not be treated with Rocephin®. The drug must not be mixed or administered simultaneously with calcium-containing solutions or products, even via different infusion lines. Additionally, calcium-containing solutions or products must not be administered within 48-hours of the last administration of ceftriaxone. Read the complete MedWatch 2007 Safety Summary including a link to the manufacturer's Dear Healthcare Professional Letter at:

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

FROM THE MEDICAL LITERATURE ...

More evidence – chocolate is good for you ... Another study has demonstrated that dark chocolate shows beneficial blood pressure lowering effects in patients with prehypertension or mild hypertension. Using “low” doses of dark chocolate (6.3 g or 30 kcal) per day (equivalent to about a couple of squares of a Hershey® Bar) the author’s demonstrated an average drop of systolic/diastolic blood pressure of approximately 3/2 mmHg in 44 adult patients over 18 weeks. They also showed that the likely mechanism is an increase of nitric oxide stimulation resulting in vasodilation. There are limitations to external validity including a small and homogenous patient population, but its still good news, particularly for chocoholics! Taubert D, Roesen R, Lehmann C, Jung N, Schömig E. Effects of low habitual cocoa intake on blood pressure and bioactive nitric oxide: A randomized controlled trial. *JAMA*. 2007 Jul 4;298(1):49-60.



Dietary education and counseling ... more bad news ... A meta-analysis of 46 trials (a total of 11,853 adult patients) involved the use of dietary counseling vs. usual care in overweight patients with body mass index (BMI) as the measure; studies ranged from 2.5 to 48 months. There were numerous limitations, including that the quality of the studies were judged to be moderate to poor. Conclusions were that dietary counseling had a small beneficial effect peaking at one year, that diminished over time. Another study conducted by the Associated Press lends support to the concept that talk is cheap. This review of studies centered on government sponsored nutrition education in schools and their effect on childhood obesity. It found that nutrition education emphasizing fruits and vegetables are largely ineffective. Some of the more successful programs also included exercise. Significant obstacles for success include: lack of parental support and participation; poverty has a significant impact; and an average of 21 TV ads per day against a short classroom lesson. Solutions are not forthcoming, but apparently just talk doesn't work. Dansigner ML, Tatsioni A, Wong JB, Chung M, Balk EM. Meta-analysis: the effect of dietary counseling for weight loss. *Ann Intern Med*. 2007 Jul 3;147(1):41-50.

Mendoza M. AP: Nutrition education ineffective. *USA Today*. 2007 Jul 4.

http://www.usatoday.com/news/health/2007-07-04-fightingfat_N.htm

Reviews of Note ...

- OTC Products: 2007 Survey of Pharmacist Recommendations. *Pharmacy Times*. 2007 Jun;73 (Suppl):1-64.
- Hudis CA. Trastuzumab – Mechanism of action and use in clinical practice. *N Engl J Med*. 2007 Jul 5;357:39-51.
- Blommel ML, Blommel AL. Pregabalin: An antiepileptic agent useful for neuropathic pain. *Am J Health-Syst Pharm*. 2007 Jul 15;64:1475-1482.
- Amori RE, Lau J, Pittas AG. Efficacy and safety of incretin therapy in type 2 diabetes: Systematic review and meta-analysis. *JAMA*. 2007 Jul 11;298(2):194-206.

FROM THE LAY LITERATURE about medicine ...

Vocabulary ... lipo-dissolve ... Also known as injection lipolysis or “flab jab,” it is a new alternative to lipo-suction. It consists of multiple small injections in specific areas of the body that are “flabby” such as the neck, chin, and abdomen; as the name implies, the intent is to dissolve fat deposits. It is also similar to “mesotherapy” which is an older procedure that uses various drugs, vitamins and herbs to try to eliminate cellulite. Lipo-dissolve usually consists of a combination of phosphatidylcholine (from soy beans) and sodium deoxycholate (a bile salt), also known as PCDC and is compounded by specialty pharmacies. Controversy surrounds its use and effectiveness; some physicians equate it to snake oil. Concerns have also been raised as to the quality of the pharmacy-compounded products (actual ingredients, sterility, etc). As are so many cosmetic procedures, it is expensive; a full treatment course, depending on the location and amount, will cost several thousand dollars.



Boodman SG. Can shots safely ‘melt away fat’?: Physicians spar over injections touted as an easy alternative to liposuction. *Washington Post*. 2007 Jun 26; p. HE01. <http://www.washingtonpost.com/wp-dyn/content/article/2007/06/22/AR2007062201870.html?referrer=email>

Pharmaceutical company influence ... again ... Two recent articles take all too common, but different, approaches to this topic. One addresses the issue of pharmaceutical company funding of continuing medical education programs. The industry’s response is that they are providing funding but have nothing to do with content; detractors say that most industry-sponsored programs are nothing more than an infomercial.

Approximately 2/3 of continuing medical education courses are funded by drug or medical device companies and between 1/3 to 1/2 of providers have relationships with the industry. Unfortunately, the article also points out the sway the industry has with Congress, dampening enthusiasm for meaningful change; and then, a change to what?

Williamson E, Lee C. Conflict alleged in drug firms’ education role. *Washington Post*. 2007 Jun 27; p. A03. <http://www.washingtonpost.com/wp-dyn/content/article/2007/06/26/AR2007062601963.html?referrer=email>

The second article targets the physicians most enriched by pharmaceutical company money and in this article, psychiatrists top the list, according to surveys to two states, Vermont and Minnesota. The amount of payments were very wide, ranging from \$51 to \$689,000; there were also correlations as to the amount of money paid and prescribing patterns of atypical antipsychotics in children. These amounts of money catch the attention of legislators and several states are in various stages of considering legislation to regulate such relationships.



Harris G. Psychiatrists top list in drug maker gifts. *New York Times*. 2007 Jun 27. http://www.nytimes.com/2007/06/27/health/psychology/27doctors.html?_r=1&oref=slogin&ref=health&pagewanted=print

Turning the corner on drug abuse ... Unfortunately, that corner is the switch from illicit to legal drugs, and the use trends continue to rise. The latest headline was that Al Gore III was busted last week for possession of marijuana, Vicodin[®], Xanax[®], Valium[®] and Adderall[®]. Apart



from alcohol which is by far the most common drug involved in toxicity and death's, Adderall[®] seems to be the most common legitimate drug taken illegally, according to a recent study of drug abuse. The primary message from this study is that the drugs in the medicine cabinet are the new favorites. They are easily accessed and they are perceived as safer; in addition, the 'stigma' of drug abuse seems to have declined in recent years. These drugs are passed around at parties, kids often don't even know what they are taking which makes it even more challenging when they enter the Emergency Room. This national problem is also very local, as two articles in the *Birmingham News* profiled data gathered from Alabama coroners and public health officials. In Jefferson county last year there were more deaths attributed to legal/illegal drugs (119) than to traffic accidents (80). Alabama had the 6th highest rate of prescription drug consumption in 2005. In addition to the rapid rise of drug abuse with prescription drugs, a problem group appears to be middle-aged black males who consume cocaine and die of myocardial infarction due to underlying heart disease. In this respect, this is not "Sweet Home Alabama."

Cohen E. Experts: Pills becoming the new marijuana on campus. *CNN.com*. 2007 Jul 5.

<http://www.cnn.com/2007/HEALTH/07/05/drug.use/index.html>

Parks D, Wilstach N. Drug deaths surge higher. *Birmingham News*. 2007 Jul 8;120(117):1,6.

<http://www.al.com/news/birminghamnews/index.ssf?/base/news/118388275028230.xml&coll=2>

Parks D. Too little treatment, too many addicts. *Birmingham News*. 2007 Jul 8;120(117):6.

<http://www.al.com/news/birminghamnews/index.ssf?/base/news/118388276628230.xml&coll=2>

AUBURN HSOP FACULTY in the literature ...

- Fox BI, Felkey BG, Berger BA, Krueger KP, Rainer Jr RK. Use of personal digital assistants for documentation of pharmacists' interventions: A literature review. *Am J Health-Syst Pharm*. 2007 Jul 15;64:1516-1525.

NEW RESOURCES in the DILRC ...

- *2007 Redbook: Pharmacy's Fundamental Reference*. Montvale, NJ: Thomson Healthcare Inc., 2007.
- *Ident-a-Drug Reference 2007*. Stockton, CA: Therapeutic Research Center, 2006.



The last "dose" ...

"Poisons and medicine are oftentimes the same substance given with different intents."

--Peter Mere Latham [1789-1875]. *General Remarks on the Practice of Medicine, Ch. IV*

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

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