

AU InforMed

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Key Inforbits

- Patch therapy for ADHD
- More information on the Bird Flu
- Pharmacists and preventable ADRs
- DTC ONLY in the U.S.
- An “unsales” force is out there
- Vaccination origins

NEW DRUGS, and other related stuff ...

New Dosage Form ... Methylphenidate transdermal system (Daytrana® by Shire Pharmaceuticals and Noven Pharmaceuticals) was approved by the FDA April 6, 2006 for patients 6 to 12 years old. It is the only “patch” approved for attention deficit hyperactivity disorder (ADHD). The patch is intended to be left on for nine hours and then removed. It’s primary intent is for those patients who have trouble with oral dosage forms. It is not without controversy, so there may be more to the story.

Dooren JC. FDA approves skin patch to treat ADHD. *Wall Street Journal* 2006 Apr 7; p. B2.

www.daytrana.com (manufacturer web site)

New Indication ... The FDA has approved a second drug for the prevention of the flu for adults and children ≥ 5 years old, on March 29, 2006. **Zanamivir (Relenza®** by GlaxoSmithKline). It has been on the market for treatment of Influenza A and B virus infections for several years. It is not recommended for patients with underlying airways disease such as asthma or chronic obstructive pulmonary disease.

FDA. FDA approves a second drug for the prevention of influenza A and B in adults and children. *FDA News*. 2006 Mar 29; P06-43.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01341.html>

NME’s ... A couple of nice reference sites from the FDA. The first URL is a list of the number of **New Molecular Entity’s (NME’s)** approved by the FDA, sorted by priority and standard reviews from 1993 to 2005. The second URL is an updated list of NME’s approved so far in 2006. This list is typically updated quarterly.

- [New Molecular Entity Drugs \(NMEs\) & New Biologics \(New BLAs\)](#)
- [NME Drug and New Biologic Approvals 2006](#)

MedWatch ... Valeant Pharmaceuticals and FDA notified healthcare professionals of complaints concerning small cracks at the base of the plastic tip of the applicators with resulting leakage of the medication when the plunger is depressed, preventing full dosing and potentially resulting in a sub-optimal therapeutic response. **Diastat® (diazepam)** is indicated for rectal administration for selected refractory epilepsy patients on stable regimens of anti-epileptic drugs, who require intermittent use of diazepam to control bouts of increased seizure activity. Advise

patients of this issue and for them to return any product with a cracked tip to their pharmacy for immediate replacement. Pharmacists should inspect all product on their shelves and contact Rx Hope at 1-800-511-2120 for replacement product.

Read the complete MedWatch 2006 Safety summary including links to the Public Health Advisory, healthcare professional and patient information sheets and Dear Healthcare professional letters, at:

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

FROM THE MEDICAL LITERATURE ...



Don't read only the abstract! ... A common admonition from DI folks, now there is more proof to back it up. A Canadian group studied meeting abstracts from the American College of Cardiology scientific meetings from 1999 to 2002, identifying late-breaking abstracts and other major papers. They then found those that were subsequently published and compared data. The "late-breaking" trials were usually larger, contained less favorable results and were published sooner than comparative RCT's. However, the discrepancy rate, that is, the difference in efficacy estimates from initial abstract to published paper was 41%. Peer review at work.

Toma M, McAlister FA, Bialy L, Adams D, Vandermeer B, Armstrong PW. Transition from meeting abstract to full-length journal article for randomized controlled trials. *JAMA*. 2006 Mar 15;295(11):1281-87.



Bird flu vaccine ... this is the study that made all of the news channels and newspapers last week, reporting on the effectiveness of the "current" avian flu vaccine. In a small study (n=451) of healthy patients, it took a relatively high dose to produce acceptable immunity in 56% of patients. This raises concerns of effectiveness, particularly in children and the elderly whose immune system may not be as robust (and untested), and the manufacturing capability to produce enough vaccine. The good news is that the vaccine appears reasonably safe. We have a long way to go, but it looks like we're headed in the right direction.

Treanor JJ, Campbell JD, Zangwill KM, Rowe T, Wolff M. Safety and immunogenicity of an inactivated subvirion influenza A (H5N1) vaccine. *N Engl J Med*. 2006 Mar 30;354(13):1343-51.

An accompanying editorial to the article above is somewhat of a plea to pay attention to, and fund appropriately, the sharing of data, international licensing, and improving manufacturing capabilities, for vaccines. The point is made that these techniques must be proven and repeatable so that the response to an imminent pandemic threat can be met in timely fashion.

Poland GA. Vaccines against avian influenza – A race against time. *N Engl J Med*. 2006 Mar 30;354(13):1411-13.

In addition, a very good review article was recently published that covers current information on the avian flu, assesses risk of a pandemic, and gives specific strategies for pharmacists. These include being immunization advocates and incorporating evaluation of immunization status to their patients.

Ford SM, Grabenstein JD. Pandemics, avian influenza A (H5N1) and a strategy for pharmacists. *Pharmacotherapy*. 2006 Mar;26(3):312-22.

Ideal doc ... Based on telephone interviews with 192 patients across a range of medical specialties in the Mayo Clinic system, investigators identified seven "ideal behaviors" that patients want to see in their physicians. These "behavior themes" are confident, empathetic, humane, personal, forthright, respectful and thorough. Suggestions are also offered as to some actions and gestures that will help convey the best message.

Bendapudi NM, Berry LL, Frey KA, Parish JT, Rayburn WL. Patients' perspectives on ideal physician behaviors. *Mayo Clin Proc*. 2006;81(3):338-344.

Pharmacists prevent ADEs ... A recent study of 178 patients demonstrated that pharmacist involvement at hospital discharge and then a follow up phone call to the patient 3 to 5 days later (reconciling discharge medications and instructions with the documentation), reduced preventable adverse drug reactions (ADEs) from 11% (control group) to 1%, at 30 days. However, total number of ADEs and total healthcare utilization remained the same; the authors state that the study was not powered to detect these differences.

Schnipper JL, Kirwin JL, Cotugno MC, Wahlstrom SA, Brown BA, Tarvin E, et al. Role of pharmacist counseling in preventing adverse drug events after hospitalization. *Arch Intern Med*. 2006 Mar 13;166:565-71.



Calcium and preeclampsia ... A study from the World Health Organization (WHO) Calcium Supplementation for the Prevention of Preeclampsia Trial Group looked at over 8000 pregnant women (<20 weeks gestation) in “non-Western” countries and compared groups with low calcium intake to a group receiving calcium supplementation. While calcium supplementation did not appear to prevent preeclampsia, it did lessen its severity, in addition, it reduced maternal morbidity and neonatal mortality. Another reason for calcium supplementation at an early age.

Villar J, Abdel-Aleem H, Merialdi M, Mathai M, Ali MM, Zavaleta N, et al. World Health Organization randomized trial of calcium supplementation among low calcium intake pregnant women. *Am J Obstet Gynecol*. 2006;194:639-49.

Direct-to-Consumer-Advertising ... Did you know that the U.S. is soon to be the only country in the world with direct-to-consumer advertising? New Zealand is the only other one and they are in the process of banning it. A rather lengthy debate paper has been published in an open-access journal that presents arguments, both pro and con. Interesting reading.

Almasi EA, Stafford RS, Kravitz RL, Mansfield PR. What are the public health effects of direct-to-consumer drug advertising? *PLoS Med* 2006 Mar;3(3): <http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030145>

Is that drug needed? ... A proposal is presented in a recent commentary article, arguing that more thought should be given to discontinuing, or not starting, medications in the elderly with limited life expectancy. A model is proposed for approaching this problem, which is often not as easy as it sounds. There are many perils along this path and many have been acknowledged. This is another ideal place for pharmacist involvement in the pharmacotherapeutic process.

Holmes HM, Hayley DC, Alexander GC, Sachs GA. Reconsidering medication appropriateness for patients late in life. *Arch Intern Med*. 2006 Mar 27;166(6):605-9.

Reviews of Note ...

- Cummins DL, Cummins JM, Pantle H, Silverman MA, Leonard AL, Chanmugam A. Cutaneous malignant melanoma. *Mayo Clin Proc*. 2006;81(4):500-507.
- Federman DD. The biology of human sex differences. *N Engl J Med*. 2006 Apr 6;354(14):1507-14.
- CDC. Diagnosis and management of tickborne rickettsial diseases: Rocky mountain spotted fever, ehrlichioses, and anaplasmosis – United States. A practical guide for physicians and other health-care and public health professionals. *MMWR*. 2006 Mar 31;55(RR-4):1-30.

FROM THE LAY LITERATURE about medicine ...



Something else for your mother to worry about ... Feeling rebellious? Want attention? How about a tongue piercing?!? Apart from the obvious immediate pain and suffering, now comes word about long term effects as well. Drawn from dental journals a recent article has highlighted some of the potential chronic problems associated with tongue piercing. These include large growths on the tongue, “another tongue,” tooth-chipping and breakage (metal against enamel), receding gums, and “tongue-splitting” literally creating a forked tongue that must be corrected surgically. I think I’ll pass ...

Weise E. ‘Not a benign operation.’ *USA Today*. 2006 Mar 27.

http://www.usatoday.com/news/health/2006-03-27-tongue-piercing_x.htm

Counter-detailing by an “unsales” force ... An article about a program in Pennsylvania, funded by the state and supported by Harvard University physicians. An “unsales” force was formed to go to physicians in the state to counter-balance pharmaceutical company sales reps. These counter-detailers (or academic detailers) present a message that emphasize the other, less expensive alternatives to the prevailing brand name drugs. Examples include over-the-counter agents instead of Nexium[®], or Tylenol[®] instead of COX-2 inhibitors. This is not a new concept, but may be catching on as the cost-benefit is shown, particularly for third-party payers. Alabama has a similar program.

Hensley S. As drug bill soars, some doctors get an ‘unsales’ pitch. *Wall Street Journal* 2006 Mar 13; p. A1.



The last “dose” ...

“Vaccination” originated from the Latin *vacca* “a cow” and *vaccinia*, or “cowpox.” This was the basis of the first successful vaccination against smallpox, using cowpox pustule material from English dairymaids, by Edward Jenner (1749-1823). The term was first used only for the inoculation material from cowpox but later was expanded to describe the injection of any microbial antigen for the purpose of inducing immunity.

-- Haubrich WS. *Medical Meanings: A Glossary of Word Origins*. 2nd ed.

Philadelphia: American College of Physicians, 2004, p. 255.



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

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