AU InforMed

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Key Inforbits

- Four new drugs!
- New product and new dose form
- New guidelines for stroke prevention
- Updated guidelines for CV disease prevention
- Vitamin myth busted??
- Article on new pharmacy residency criteria

NEW DRUGS, and other related stuff …

New Drug … The FDA approved rasagiline mesylate (Azilect® by Teva Pharmaceutical Industries Ltd.) on May 17, 2006. Rasagiline mesylate, a monamine oxidase type-B (MAO-B) inhibitor, is indicated for the once-daily treatment of various stages of Parkinson's disease. It may be used as an initial treatment, or in combination with levodopa. Melanoma developed as a concern during development and will be the subject of phase IV investigations.

FDA. FDA approves new treatment for Parkinson's Disease. *FDA News*. 2006 May 17; P06-68.
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01373.html

New Drug … The FDA approved a biologics license application for the first treatment of Pompe Disease, alglucosidase alfa, rhGAA (Myozyme® by Genzyme) on April 28, 2006. Alglucosidase alfa is indicated for use in patients with Pompe disease (GAA deficiency) and has been shown to improve ventilator-free survival in patients with infantile-onset disease. Pompe disease is a rare but severely debilitating disease drastically reducing muscle and respiratory function. It is an inherited disease caused by the deficiency or lack of the enzyme acid alpha-glucosidase, which is essential for normal muscle development and function. The disease, which usually results in death from respiratory failure, is rapidly fatal in newborn babies. It afflicts less than 10,000 patients world-wide; the treatments will cost about $200,000 to $300,000 per year.

Pollack A. Genzyme's drug for rare enzyme deficiency is approved. *New York Times.com* 2006 Apr 29.
http://www.nytimes.com/2006/04/29/business/29drug.html
http://www.myozyme.com/ (Genzyme web site)

New Drug … The FDA announced on May 3, 2006, the approval of decitabine (Dacogen™ manufactured by Pharmachemie B.V. Haarlem for MGI Pharma, Inc). Decitabine is indicated for treatment of patients with myelodysplastic syndromes (MDS), as it is thought to work by promoting normal development of blood cells. MDS afflicts 7,000 to 12,000 new patients each year and thus was granted orphan drug status. Decitabine should be available mid-2006.

FDA. FDA approves new treatment for myelodysplastic syndromes (MDS). *FDA News*. 2006 May 3; P06-64.
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01366.html
http://www.dacogen.com/ (Manufacturer web site)

New Drug … The FDA approved a new smoking cessation agent May 11, 2006, varenicline tablets (Chantix™ by Pfizer). It appears to act in two ways, 1) eases withdrawal by providing some nicotine effects and 2) blocking nicotine effects if the user resumes smoking. Labeling

calls for a treatment course of 12 weeks with an option for an additional 12 weeks. Common side effects include nausea/vomiting, headache, flatulence, insomnia, dreams and dysguesia.
FDA. FDA approves novel medication for smoking cessation. *FDA News*. 2006 May 11; P06-67.
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01370.html
http://www.chantix.com/ (Pfizer web site)

New Indication ... On May 19, 2006, the FDA approved infliximab (Remicade® by Centocor, a unit of Johnson & Johnson) to treat children with active Crohn's disease, a chronic, inflammatory condition of the bowel that can be severely debilitating. It was initially approved in 1998 to treat Crohn's disease in adults. Pediatric risks are described in the May 17 issue of *JAMA*, and are included in the current labels for all approved TNF-alpha blocking agents.
FDA. FDA approves Remicade for children with crohn's disease. *FDA News*. 2006 May 19; P06-71.
http://www.fda.gov/bbs/topics/NEWS/2006/NEW01376.html

New Product … Valeant Pharmaceuticals International announced on May 16, 2006 that the FDA has given marketing approval for nabilone (Cesamet™ (CII)) oral capsules. Nabilone is used to treat nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional anti-emetic treatments. Nabilone is a synthetic cannabinoid thought to act as an omnineuromodulator – interacting with cannabinoid receptors, in the nervous system which are involved in regulating nausea and vomiting. Cesamet™ has a long duration of action, which allows for less frequent dosing, typically twice daily. Valeant acquired Cesamet™ from Eli Lilly & Company in 2004 and currently sells it in Canada. Last year, Valeant entered into an agreement with Par Pharmaceutical Companies to promote the product in the United States. Product launch is expected in the next several weeks.
http://www.valeant.com/mediaCenter/newsArticle/newsArticle.jspf;jsessionid=FE7E9B2E333A8B07928A480C7B4DDBF1.frank?objectId=4158

New Dose Form … The FDA has approved an injectable form of naltrexone (Vivitrol™ by Cephalon) for the treatment of alcohol dependence. Vivitrol™ is the first monthly injectable medication for alcohol dependence, and is indicated for alcohol dependent patients who are able to abstain from alcohol in an outpatient setting and are not actively drinking when initiating treatment. Treatment with Vivitrol™ should be used in a comprehensive management program that includes psychosocial support. The product should be available this summer.
http://www.ptcommunity.com/Daily/DailyDetail.cfm?chosen=64600
http://www.vivitrol.com/ (Cephalon web site)

MedWatch … The FDA is recommending that all healthcare providers take important safety steps when using the COLLEAGUE Volumetric Infusion Pump manufactured by Baxter Healthcare Corporation. The COLLEAGUE pump has exhibited a variety of problems, including under-infusion, battery failures, false alarms and failure to alarm. Over the past year, Baxter has issued four urgent safety notices and recalls for COLLEAGUE infusion pumps. In addition to the recommendations made by Baxter Healthcare Corporation when using the COLLEAGUE Volumetric Infusion Pump, the FDA is strongly recommending the following measures:

- Do not use the COLLEAGUE pumps where delaying or interrupting therapy in order to reprogram or replace a malfunctioning pump may be life threatening, if possible.
- Have a contingency plan to mitigate any disruption of infusion therapy (e.g., have a back-up pump available).

- Monitor patients and check the pumps frequently.
- Report any problems as soon as possible to Baxter and FDA.
- Consider evaluating other options for infusion therapy if your facility relies primarily or entirely on COLLEAGUE Pumps.

Other short-term options that may be appropriate for certain IV therapies include gravity drip and flow control devices (e.g., buretrol, volutrol, micro tubing, and flow control tubing devices). Read the complete MedWatch 2006 Safety summary, including a link to the FDA Preliminary Public Health Notification, at:
http://www.fda.gov/medwatch/safety/2006/safety06.htm#colleague2

FROM THE MEDICAL LITERATURE …

Guidelines … New stroke-prevention guidelines are available centering on the primary prevention of stroke. The guidelines identify a variety of specific factors that increase the risk of a first stroke, and provides recommendations to reduce the risk. Among other things, one of the recommendations is to provide statins to patients who have diabetes mellitus and a high risk of stroke. The following link provides access to the full 52 page report.
Goldstein LB, Adams R, Alberts MJ, Appel LJ, Brass LM, Bushnell CD, et al. Primary prevention of ischemic stroke. A guideline from the American Heart Association/American Stroke Association Stroke Council: Cosponsored by the Atherosclerotic Peripheral Vascular Disease Interdisciplinary Working Group; Cardiovascular Nursing Council; Clinical Cardiology Council; Nutrition, Physical Activity, and Metabolism Council; and the Quality of Care and Outcomes Research Interdisciplinary Working Group. *Stroke*. 2006;37:0000-0000.
http://stroke.ahajournals.org/cgi/reprint/01.STR.0000223048.70103.F1v1

Guidelines Updated … New guidelines on preventing further problems for patients with atherosclerotic vascular disease state that a low-density-lipoprotein cholesterol concentration of less than 70 mg/dL is a "reasonable" goal. The guidelines, released May 15 by the American Heart Association and American College of Cardiology, also recommend limiting low-dose aspirin therapy to no more than 162 mg/day.
Smith SC, Allen J, Blair SN, Bonow RO, Brass LM, Fonarow GC, et al. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update. *Circulation*. 2006;113:2363-2372.
http://circ.ahajournals.org/cgi/reprint/113/19/2363

One-A-Day wasted? … According to the National Institutes of Health (NIH), State-of-the-Science Conference Statement, there is still insufficient evidence to recommend or not recommend, using multivitamin and multiple-mineral supplements to prevent chronic disease in generally healthy adults. Just when you thought you had a handle on it, someone subjects the principle of scientific review. Part of the problem is the lack of rigorous trials, and that it's difficult to discern differences in already healthy people. It's a nice review of the evidence.
National Institutes of Health (NIH), State-of-the-Science Conference Statement: Multivitamin/mineral supplements and chronic disease prevention, May 17, 2006.
http://consensus.nih.gov/2006/MVMDRAFT051706.pdf

Reviews of Note …

- Top 200 OTC/HBC brands in 2005. *Drug Topics*. 2006 Apr 17;150(8):40, 42.
www.drugtopics.com

- Mauck KF, Clarke BL. Diagnosis, screening, prevention, and treatment of osteoporosis. *Mayo Clin Proc*. 2006;81(5):662-72.

Update …

Teeters JL. New ASHP pharmacy residency accreditation standards. *Am J Health-Syst Pharm*. 2006 Jun 1;63:1012, 1014, 1018.

NEW RESOURCES in the DILRC …

- Straus SE, Richardson WS, Glasziou, Haynes RB. *Evidence-based Medicine: How to Practice and Teach EBM*. 3rd ed. London: Elsevier Churchill Livingstone, 2005.
- Abood R. *Pharmacy Practice and the Law*. 4th ed. Boston: Jones and Bartlett, 2005.
- Talavera F, Scholar EM. *Rapid Fire Pharmacy Review*. 2nd ed. Boston: Jones and Bartlett, 2006.
- Briggs GG, Freeman RK, Yaffe SJ. *Drugs in Pregnancy and Lactation*. 7th ed. Baltimore: Lippincott, Williams and Wilkins, 2005.
- Landefeld CS, Palmer RM, Johnson MA, Johnston CB, Lyons WL, eds. *Current Geriatric Diagnosis & Treatment*. NY: Lange Medical Books/McGraw-Hill, 2004.
- Beers MH, ed. The Merck Manual of Diagnosis and Therapy. 18th ed. Whitehouse Station, NJ: Merck Research Laboratories, 2006.

AUBURN HSOP FACULTY and STUDENTS in the literature …

- Andrus MR, Donaldson AR. Outcomes of a lipid management program in a rural nurse practitioner clinic. *Ann Pharmacother*. 2006 Apr;40(4):782. [letter]
- Villaume WA, Berger BA, Barker BN. Learning motivational interviewing: Scripting a virtual patient. *Am J Pharm Ed*. 2006;70(2):Article 33.
- Field L. Thomas appointed to Auburn historic commission. *Opelika-Auburn News*. 2006 May 20;101(140):3A. [***Article on Dr. Susie Thomas, HSOP faculty, who was recently appointed to the Auburn Historic Preservation Commission***]

The last "dose" …

"One should treat as many patients as possible with a new drug while it still has the power to heal."
--Sir William Osler [1849-1919]

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