

# AU InforMed

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## Key Inforbits

- New guidelines for IBS
- Immunization schedules revised, adults & kids
- “Standards of Care” for Diabetes by the ADA
- Cyberchondria!?!?
- Statins for everyone!
- Chain pharmacy and State Boards

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

**New Dose Form** ... (1/5/2009) CyDex Pharmaceuticals and Prism Pharmaceuticals announced a new product, **Nexterone<sup>®</sup> (amiodarone)**. Amiodarone has been on the market for years but this is a special (patented) formulation of the intravenous dose form (in single use glass vials and prefilled syringes) that eliminates some of the preservatives/solvents that have sometimes been problematic in the past. The product is indicated as an antiarrhythmic agent for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. <http://www.prismpharma.com/nexterone.html> (Prism Pharmaceutical; package insert available) <https://www.cydexpharma.com/news.html> (CyDex Pharmaceutical press release)

**MedWatch** ... (12/11/2008) There are reports of **acute phosphate nephropathy, a type of acute kidney injury, associated with the use of oral sodium phosphate products (OSP) for bowel cleansing** prior to colonoscopy or other procedures. These products include the prescription products, Visicol<sup>®</sup> and OsmoPrep<sup>®</sup>, and OSPs available over-the-counter as laxatives (e.g., Fleet Phospho-soda<sup>®</sup>). In some cases, these serious adverse events have occurred in patients without identifiable factors that would put them at risk for developing acute kidney injury. FDA is requiring the manufacturer of Visicol<sup>®</sup> and OsmoPrep<sup>®</sup>, to add a Boxed Warning to the labeling for these products. FDA is also requiring that the manufacturer develop and implement a risk evaluation and mitigation strategy (REMS), which will include a Medication Guide, and to conduct a postmarketing clinical trial to further assess the risk of acute kidney injury with use of these products. FDA recommends that over-the-counter laxative OSP products should not be used for bowel cleansing. Consumers should only use OSPs for bowel cleansing pursuant to a prescription from a healthcare professional. Read the MedWatch 2008 safety summary, including a link to the FDA Drug Information Page, at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#OSP>

**MedWatch** ... (12/22/2008) The FDA alerted consumers nationwide not to purchase or consume **more than 25 different products marketed for weight loss because they contain undeclared, active pharmaceutical ingredients** that may put consumers' health at risk. The undeclared active pharmaceutical ingredients in some of these products include sibutramine (a controlled substance), rimonabant (not approved in the US), phenytoin (an anti-seizure medication), and phenolphthalein (a chemical reagent and a suspected cancer causing agent). The weight loss products, some of which are marked as "dietary supplements," are promoted and sold on various

web sites and in some retail stores. The FDA advises consumers who use the products to stop taking them and consult their healthcare professional immediately as the health risks posed by these products can be serious. See the FDA News Release for a listing of the names of the 25 referenced products.

Read the MedWatch 2008 safety summary, including links to the News Release and Questions and Answers, at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Weight> (FDA MedWatch)

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01933.html> (FDA News Release)

**MedWatch** ... (12/24/2008) ETHEX and the FDA notified healthcare professionals of a **nationwide recall of a single lot of Hydromorphone HCl 2 mg Tablets** due to potential for oversized tablets. Hydromorphone is a drug used for pain management. If someone were to take a higher than expected dose of Hydromorphone, the risk of adverse effects known to be associated with the drug may be increased, including respiratory depression (difficulty or lack of breathing), low blood pressure, and sedation. The recalled tablets are a blue, round tablet with a script "E" on one side and a "2" on the other side.

Read the complete MedWatch 2008 Safety summary, including links to the Ethex and KV press releases and a list of KV products affected by the suspension, at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#Hydromorphone>

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

**Guidelines ... Irritable Bowel Syndrome ...** The American College of Gastroenterology has published an update to their 2002 monograph on Irritable Bowel Syndrome (IBS). They have systematically reviewed all the major therapies for IBS and offered an assessment of the evidence for effectiveness. Therapies range from herbal remedies to psychological therapies and the pharmacological options in between.

Brandt LJ, Chey WD, Foxx-Orenstein AE, Schiller LR, Schoenfeld PS, Spiegel BM, et al for the American College of Gastroenterology Task Force on Irritable Bowel Syndrome. An evidence-based systematic review on the management of irritable bowel syndrome. *Am J Gastroenterol.* 2009 Jan;104(Suppl 1):S1-S36.

**Immunization schedule for children, revised ...** Some of the changes from the previous schedule include: Changes of age recommendations for rotavirus vaccines; routine annual influenza vaccination is recommended for all children aged 6 months through 18 years; the minimum interval between tetanus and diphtheria toxoids (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) for persons aged 10 through 18 years is addressed; information about the use of Haemophilus influenzae type b (Hib) conjugate vaccine among persons aged 5 years and older at increased risk for invasive Hib disease has been added; catch-up vaccination with human papillomavirus (HPV) vaccine is clarified; and abbreviations for rotavirus, pneumococcal polysaccharide and meningococcal polysaccharide vaccines have been changed. The full schedule is available from the CDC. Centers for Disease Control and Prevention. Recommended Immunization Schedules for Persons Aged 0 Through 18 Years-United States, 2009. *MMWR.* 2009 Jan 2;57(51):Q1-Q4.



<http://www.cdc.gov/mmwr/PDF/wk/mm5751-Immunization.pdf>

**Immunization schedule for adults, revised ...** In October 2008, the Advisory Committee on Immunization Practices (ACIP) approved the Adult Immunization Schedule for 2009. No new vaccines were added to the schedule; however, several indications were added to the

pneumococcal polysaccharide vaccine footnote, clarifications were made to the footnotes for human papillomavirus, varicella, and meningococcal vaccines, and schedule information was added to the hepatitis A and hepatitis B vaccine footnotes. The full schedule is available from the CDC.

Centers for Disease Control and Prevention. Recommended Adult Immunization Schedule - United States, 2009. MMWR. 2009 Jan 9;57(53):Q-1-Q-4.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5753a6.htm>

**Standards of Care** ... The new standards of medical care for **diabetes** have been published. This 49 page document provides recommendations for screening, diagnostic and therapeutic actions that favorably affect health outcomes for diabetic patients. A grading system developed by the American Diabetes Association is included to help determine/clarify the level of evidence for each recommendation.



American Diabetes Association. Standards of medical care in diabetes – 2009. Diabetes Care. 2009 Jan;32(Suppl 1):S13-S61.

### Reviews of Note ...

- Thomsen A, Kolesar JM. Chemoprevention of breast cancer. Am J Health-Syst Pharm. 2008 Dec 1;65:2221-2228.
- Frishman WH. Fifty years of beta-adrenergic blockade: A golden era in clinical medicine and molecular pharmacology. Am J Med. 2008 Nov;121(11):933-934.
- Alleyne M, Horne MK, Miller JL. Individualized treatment for iron-deficiency anemia in adults. Am J Med. 2008 Nov;121(11):943-948.
- LeWitt PA. Levodopa for the treatment of Parkinson's Disease. N Engl J Med. 2008 Dec 4;359(23):2468-2476.
- Zed PJ, Abu-Laban RB, Shuster M, Green RS, Slavik RS, Travers AH. Update on cardiopulmonary resuscitation and emergency cardiovascular care guidelines. Am J Health-Syst Pharm. 2008 Dec 15;65:2337-2346.
- Williams NT. Medication administration through enteral feeding tubes. Am J Health-Syst Pharm. 2008 Dec 15;65:2347-2357.
- Abramowicz M, ed. Drugs for postmenopausal osteoporosis. Treatment Guidelines Med Lett. 2008 Oct;6(74):67-74.

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

**Vocabulary** ... **Cyberchondria** ... “the practice of leaping to dire conclusions while researching health matters online.” Microsoft published a recent study looking at the trends of health-related



web searches. They found a lot of cyberchondria. One example was to search “headache” and users would focus on results related to brain tumors rather than more mundane (and likely) causes such as caffeine withdrawal. This research found that approximately 2% of all Web queries were health related and about 1/3 of these escalated their initial searches to delve into serious illnesses. These propensities are nothing new and part of human behavior, but now they have a powerful new ally.

Markoff J. Microsoft examines causes of ‘cyberchondria.’ New York Times. 2008 Nov 25.

[http://www.nytimes.com/2008/11/25/technology/internet/25symptoms.html?\\_r=1&ref=health](http://www.nytimes.com/2008/11/25/technology/internet/25symptoms.html?_r=1&ref=health)

**Chain pharmacies – too much influence?** ... A *USA Today* article calls into question the number of chain pharmacies represented on state boards of pharmacy. Overall, chain pharmacy members occupy about 25% of state board of pharmacy seats. This is not unexpected as chain pharmacies employ a large number of pharmacists. However, some of the members occupy influential positions with their company (eg, national director of pharmacy affairs at Walgreens, vice president of pharmacy services for Rite Aid, director of pharmacy services for Wal-Mart, pharmacy regulatory affairs manager for Target) and influential positions on the state board (eg, president). In addition, the article points out the potential conflict of interest at last year's National Association of Boards of Pharmacy meeting, where the National Association of Chain Drug Stores hosted a \$21,000 reception. Et tu Brute?



McCoy K. Chains' ties run deep on pharmacy boards. *USA Today*, December 31, 2008.

[http://www.usatoday.com/money/industries/health/2008-12-30-pharmacies-boards-mistakes-prescriptions\\_N.htm](http://www.usatoday.com/money/industries/health/2008-12-30-pharmacies-boards-mistakes-prescriptions_N.htm)

**Statins for everyone** ... An article from Los Angeles (where else?) that presents a reasonably balanced view of the recent evidence of statins (HMG-CoA reductase inhibitors) and their apparent multitude of benefits, even in reasonably healthy individuals. After presenting some of the various diseases that seem to benefit from statin therapy, in addition to elevated cholesterol, such as multiple sclerosis, cancers and Alzheimer's, several physicians weigh in with characteristic (and appropriate) caution and the need for "more data." However, the seed is planted!



Davis EC. Should statins be available for everyone? *Los Angeles Times*, December 22, 2008.

<http://www.latimes.com/features/health/la-he-statin22-2008dec22.0,1365967.story>

**Drug Interxn's with ED drugs** ... The Washington-based watch-dog group Public Citizen (Sidney Wolfe, MD is their primary spokesman) has posted a list of 56 drug interactions with erectile dysfunction drugs (sildenafil [Viagra<sup>®</sup>], vardenafil [Levitra<sup>®</sup>], and tadalafil [Cialis<sup>®</sup>]) along with warnings of the dangers of these combinations, so you may be getting additional questions. The interactions center around vasodilators (nitrates, alpha blockers) and drugs metabolized by the CYP3A4 enzyme system. One estimate is that 10% to 20% of the US male population could be candidates for these drugs.



Larkin C. Erection drugs may pose risks with other treatments. *Bloomberg*, January 5, 2009.

<http://www.bloomberg.com/apps/news?pid=newsarchive&sid=as7D5M4jdwGA#>

### **AUBURN HSOP FACULTY and STUDENTS in the literature ...**

- Fox BI, Felkey BG, Fortier C. The environment of e-prescribing and its impact on the pharmacy department. *Hosp Pharm*. 2009 Jan;44(1):77, 78, 80.



### **The last "dose" ...**

"Work is either fun or drudgery. It depends on your attitude."

--Colleen C. Barrett [1944 - ], President Emeritus of Southwest Airlines

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