

AU InforMed

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Key Inforbits

- **DANGER!** For children under 2
- Routine immunization schedules updated
- FDA going after unapproved drugs
- DEMANDING generic insulin
- Technology prescribed in many areas ...
- Have you been “plutoed!!”

NEW DRUGS, and other related stuff ...

MedWatch ... On 12/14/2006, safety-related drug labeling changes for October 2006 were posted on the MedWatch website. The October 2006 posting includes 47 drug products with safety labeling changes to the Boxed Warning, Contraindications, Warnings, Precautions, Adverse Reactions, and Patient Package Insert/Medication Guide sections.

The Summary page --

http://www.fda.gov/medwatch/SAFETY/2006/oct06_quickview.htm

-- provides drug names and a listing of the sections changed.

The Detailed view --

<http://www.fda.gov/medwatch/SAFETY/2006/oct06.htm>

-- includes sections/subsections changed and a description of new or modified safety information in the Boxed Warning, Contraindications, or Warnings sections. The full labeling may be accessed by clicking on the drug name in the detailed view.

FROM THE MEDICAL LITERATURE ...

They REALLY MEAN not recommended under the age of 2 years ... A recent report from the CDC cites three infant deaths in 2005 due to treatment (likely over-treatment) with cough/cold preparations, primarily to the pseudoephedrine content. In addition, during 2004-2005 there were 1519 children <2 years admitted to emergency rooms also due to adverse reactions and overdoses to cough/cold medications. It is unknown if this age bracket has significant metabolic differences. Reviews of controlled studies indicate these preparations are no more effective than placebos, and clinical practice guidelines recommend against their use. The message is clear.

Pediatric Toxicology Committee and Data Committee, National Association of Medical Examiners. Infant deaths associated with cough and cold medications – Two states, 2005. *MMWR*. 2007 Jan 12;56(1):1-4.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm>

MedWatch has also issued an alert with additional information. Read the complete MedWatch 2007 Safety summary, including another link to the MMWR article, at:

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



Immunization schedules for ages 0 to 18 years updated ... Changes from last year include adding the new rotavirus vaccine; incorporating the updates for the influenza vaccine for all children; varicella vaccine recommendations are updated; and the new human papillomavirus vaccine (HPV) is added. Also, the schedule format is changed and divided into

two schedules, one for persons aged 0 to 6 years and another for those aged 7 to 18 years. The schedules are provided in text as well as a full-color .pdf file.

Recommended immunization schedules for persons aged 0-18 years – United States, 2007. *MMWR*. 2007 Jan 5;55(51-52):Q1-Q4.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5551a7.htm> [text file]

<http://www.cdc.gov/mmwr/PDF/wk/mm5551-Immunization.pdf> [pdf file]

Reviews of Note ...

- Martell BA, O'Connor PG, Kerns RD, Becker WC, Morales KH, Kosten TR, et al. Systematic review: Opioid treatment for chronic back pain: Prevalence, efficacy, and association with addiction. *Ann Intern Med*. 2007 Jan 17;146(2):116-127.
- Santaella RM, Fraunfelder FW. Ocular adverse effects associated with systemic medications. *Drugs*. 2007;67(1):75-93.
- Keating GM, Croom KF. Fenofibrate: A review of its use in primary dyslipidaemia, the metabolic syndrome and type 2 diabetes mellitus. *Drugs*. 2007;67(1):121-53.
- Ropper AH, Gorson KC. Concussion. *N Engl J Med*. 2007 Jan 11;356(2):166-72.

FROM THE LAY LITERATURE about medicine ...

Personal Health Record ... So many things today are transformed with technology (eg, banking), but electronic medical records have lagged behind, and in particular patients as keepers of their medical records. Several services have “come on line” to help patients to maintain their own medical records, and not all of it can be electronic. Some of the more active users actually utilize it for family members (eg, children, elderly). Included in the article are suggestions on how to get started and what to include in your records.

Stahl L (of *The Louisville Courier-Journal*). Technology helps patients take charge of health records. *USA Today*. 2007 Jan 5.

http://www.usatoday.com/news/health/2007-01-06-phr_x.htm



OK, OK, now we're serious ... There are approximately 2% of prescription **drug products that have never undergone FDA approval** and who knows how many OTC products. While the FDA does get some off the market (most recently, some quinine-containing products), many of these drugs have been on the market for years and most health professionals have no idea. The FDA announced to 65 companies on January 9, 2007 that it plans to step up efforts to remove these products. While many are probably not dangerous, they may be ineffective and they definitely bypass the FDA's mandate to assure safe and effective drug products.

Rubin R. FDA to sweep unapproved drugs off the market. *USA Today*. 2006 Jan 9.

http://www.usatoday.com/news/health/2007-01-09-drugs-fda_x.htm

Demanding generic insulin ... State Medicaid agencies spend a significant amount of their budget on insulin. This is due to the “epidemic” of diabetes sweeping the U.S., and the expense of insulin products. There are no generic human insulin's and thus the price is under the control of brand name pharmaceutical manufacturers. Part of the reason that there are no generics is that the FDA has not followed through on its promise to provide guidelines for approving generic insulin and human growth hormone. To be sure, production of biomanufactured insulin is more complicated than in the days of using beef and pork pancreas, but it is clear the primary

motivation is the protection of profits. With governors and legislators weighing in, change may not be too far off.

Saul S. Bridling at insulin's cost, states push for generics. *New York Times*. 2007 Jan 11.

http://www.nytimes.com/2007/01/11/business/11insulin.html?_r=1&ref=health&oref=slogin

ePrescribing may be soon ... Sloppy handwriting is nothing new; cleaning it up may be close. This Tuesday a new program is being introduced. The National e-prescribing Patient Safety Initiative (NEPSI) is offering physicians access to eRx Now, a web-based tool to eprescribe and check drug interactions. This is a partnership of several companies such as Google, Dell, Aetna and numerous hospitals with the stated goals of reducing medication errors (save money for insurance companies) and push along physicians to full electronic medical records. Physician offices and pharmacies will need to be connected.



Caplan J. Cause of death: Sloppy doctors. *Time* and CNN. 2007 Jan 15.

<http://www.time.com/time/health/article/0,8599,1578074,00.html>

Coumadin® Clinics may be changing ... several studies are underway to use gene mapping to identify the perfect personal warfarin dose. The initiative is being driven by PBM, Medco Health Solution. If it pans out as expected, the potential cost savings could be huge. Lots of numbers are cited as to bleeding episodes and hospitalizations that can be prevented; also lots rhetoric about the long-term benefit/potential of personalized medicine. No discussion of the downsides and the inevitable ethical dilemma's.

Johnson LA. Personalizing medicine: Researchers study how genes affect proper dosages. *USA Today*. 2007 Jan 13.

http://www.usatoday.com/news/health/2007-01-13-personalizedmedicine_x.htm



Fighting-mad Physicians ... the retail-based clinics (RBC) are catching the attention of physicians and they are generally not happy. These are the MinuteClinic, RediClinic, QuickClinic, etc that are popping up in retail establishments, mostly large chain pharmacies, and big-box retailers such as Wal-Mart, offering quick service for vaccinations, colds/flu/strep throat/ear infections, etc. The American Medical Association and the American Academy of Pediatrics are both opposed to them. They decry the loss of continuity of care and, frankly, income. Based on this article, there is a place for both. Are some of these vocal physicians the same ones that advocate the use of vending machines in their practice to dispense medications?

Mishori R. Is 'Quick' enough? *Washington Post*. 2007 Jan 16; p. HE01.

<http://www.washingtonpost.com/wp-dyn/content/article/2007/01/12/AR2007011201858.html?referrer=email>

AUBURN HSOP FACULTY in the literature ...

- Ducharme MM, Boothby LA. Analysis of adverse drug reactions for preventability. *Int J Clin Pract*. 2007 Jan;61(1):57-61.

NEW RESOURCES in the DILRC ...

- Sweetman SC, ed. *Martindale: The Complete Drug Reference*. 35th ed, 2 volumes. London: The Pharmaceutical Press, 2007.
- Davis NM. *Medical Abbreviations: 28,000 Conveniences at the Expense of Communication and Safety*. 13th ed. Warminster, PA: Neil M. Davis Associates, 2007.

- Konnor DD, ed. *Pharmacy Law Desk Reference*. NY: Haworth Press, 2007.
- Shargel L, Mutnick AH, Souney PF, Swanson LN, eds. *Comprehensive Pharmacy Review*. 6th ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer Health, 2007.
- Tatro DS, ed. *Drug Interaction Facts 2006*. St. Louis: Facts and Comparisons/Wolters Kluwer Health, 2006.
- Ansel HC, Stoklosa MJ. *Pharmaceutical Calculations*. 12th ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer Health, 2006.
- Schrier RW, ed. *Diseases of the Kidney & Urinary Tract*. 8th ed, 3 volumes. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer Health, 2007.

TIMELY TOP TECH TIP ...

Big Brother is doing more than watching ... A real estate agent is “followed” through a days activities recounting how many times her movements and actions are recorded, stored (potentially for years), and used (potentially for targeted advertisements, but could come back to be bothersome, eg, divorce). If you haven’t thought about how much “they” know about you, this should open your eyes.



Nakashima E. Enjoying technology’s conveniences but not escaping its watchful eyes. *Washington Post*. 2007 Jan 16; p. A01.

<http://www.washingtonpost.com/wp-dyn/content/article/2007/01/15/AR2007011501304.html?referrer=email>

If it’s true, are you still paranoid? ... Much data that you think is private is actually stored on third party servers and so far, that means the government has great access. Both government agencies and those with even more nefarious intents, are looking for ways to exploit these wide-open fields. It gives “data-mining” a whole new context.

Nakashima E. The legal tangles of data collection. *Washington Post*. 2007 Jan 16; p. A09.

<http://www.washingtonpost.com/wp-dyn/content/article/2007/01/15/AR2007011501301.html?referrer=email>



The last “dose” ... vocabulary

- Plutoed -

“to demote or devalue someone or something”

Chosen as the Word of the Year for 2006 by the American Dialect Society



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

Auburn University, Harrison School of Pharmacy, Drug Information Center

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