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NEW DRUGS, and other related stuff ...

New Vaccine ... Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (*Menactra* by Aventis Pasteur) was approved by the FDA on January 14, 2005.

http://www.usatoday.com/news/health/2005-01-17-men_x.htm

New OTC Dose Form ... The FDA approved a generic over-the-counter product, potassium iodide oral solution, 65mg/ml (ThyroShield™ by Fleming & Company) as a thyroid blocking agent in radiation emergencies, on January 12, 2005. drugs@FDA.gov

New Dose Form ... The FDA announced January 7, 2005 the approval of Abraxane™ for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension by American Pharmaceutical Partners, Inc. and American Bioscience, Inc.). Abraxane™ is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. The approval marks a new class of "protein-bound particle" drugs, now made possible by ABI's proprietary nanoparticle albumin-bound (nab™) technology.

<http://www.appdrugs.com/010705PR.html> (Press Release)

<http://www.abraxane.com/index.htm#> (Prescribing information)

New Dose Form ... The FDA approved an oral solution dose form for aripiprazole (Abilify® by Bristol-Myers Squibb and Otsuka Pharmaceutical) on January 4, 2005. The oral solution formulation will be available in pharmacies in February 2005.

http://www.bms.com/news/press/data/pf_press_release_5280.html (Press Release)

New Test ... by Roche, *AmpliChip CYP450*, that analyzes variations in two genes that affect drug metabolism, with a big impact on drug interactions. In Europe the test costs about \$525, but it is a one-time test. It is expected to be available in the U.S. in March.

Dow Jones Newswires. FDA approves Roche gene test that aids in adjusting drug doses. *Wall Street Journal online* 2005 Jan 11.

MedWatch ... The FDA and Wyeth notified pharmacists and physicians of a new Medication Guide for Cordarone® (amiodarone HCl tablets). A Medication Guide is to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. A list of currently approved Medication Guides are available at <http://www.fda.gov/cder/Offices/ODS/labeling.htm>.

Read the 2005 safety summary, including links to the Dear Healthcare Professional Letter, Dear Pharmacist Letter, current Prescribing Information, and new Medication Guide:

<http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Cordarone>

ADHD drug recall ... According to the Washington Post, Alliant Pharmaceuticals recalled 500 bottles of *Methylin Chewable Tablets*, 5 mg (methylphenidate) due to the tablets having potentially as much as three times the labeled active ingredient. Lot # AMT50402A.
<http://www.washingtonpost.com/wp-dyn/articles/A11075-2005Jan14.html>

FROM THE MEDICAL LITERATURE ...

New OTC ... **NOT** ... An FDA Advisory Committee rejected the proposal to move lovastatin (Mevacor[®] by Merck and Johnson & Johnson) to over-the-counter (OTC) status, in a 20-3 vote. This is the second rejection in four years. The general feeling seems to be that more medical oversight is needed for such a drug and disease.

Stein R. Nonprescription sales of cholesterol drug rejected. *Washington Post* 2005 Jan 15; p. A03.

<http://www.washingtonpost.com/wp-dyn/articles/A9916-2005Jan14.html>

But wait! ... Bristol Myers Squibb is moving ahead with its request to move Pravachol[®] (pravastatin) to OTC status. They also have tried before and failed. Perhaps it will all be in the plan and presentation as to ultimate success?

Rubin R. Another cholesterol drug seeks OTC status. *USA Today.com* 2005 Jan 16.

http://www.usatoday.com/news/health/2005-01-16-cholesterol-usat_x.htm

Mechanism of statins in Alzheimers ... Alzheimer disease is characterized by accumulation of amyloid deposits in the brain that are composed of amyloid-beta (A β) peptide, a protein fragment that is cleaved off from the amyloid precursor protein (APP). APP can be cleaved in two ways. Amyloidogenic ("amyloid generating") cleavage by the enzyme beta-secretase yields "sticky" (A β) peptides that aggregate to form deposits, whereas non-amyloidogenic cleavage by alpha-secretases generates soluble peptides that do not form deposits. Studies in animal models and cell culture suggest that statins might modulate APP processing and shift the balance toward "healthy" cleavage. Investigators focused on a molecule called ROCK, a kinase enzyme that had recently been implicated in APP processing. Working in mouse neuroblastoma cells, they confirmed that two different statins increased healthy cleavage of APP; ROCK might be a suitable target for drugs that promote healthy cleavage of APP.

Pedrini S, Carter TL, Prendergast G, Petanceska S, Ehrlich ME, et al. (2005) Modulation of Statin-Activated Shedding of Alzheimer APP Ectodomain by ROCK. *PLoS Med* 2(1): e18. [Available as free access from PLoS Medicine (www.plosmedicine.org)]

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0020018>

Vaccine schedule ... The childhood and adolescent immunization schedule for 2005 is unchanged from that published in April 2004. In addition, the catch-up immunization schedule for children and adolescents who start late or who are >1 month behind remains unchanged from that published in April 2004. The childhood and adolescent immunization schedule and the catch-up immunization schedule for 2005 have been approved by ACIP, AAFP, and AAP. CDC. Recommended childhood and adolescent immunization schedule – United States, 2005. *MMWR* 2005 Jan 7;53(51):Q1-Q3

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5351-Immunization1.htm>

FROM THE LAY LITERATURE about medicine ...

Bad News ... Nothing has changed over the last year as to the secrets of good health and long life. The axioms are still: Be active; eat smart; control weight; don't smoke; get enough sleep; control stress. A good article to summarize the stubbornly unchanging, unforgiving, in-your-face, common sense.

Stolz C, Payne JW. A prevent defense: You can greatly reduce risk of most aging-related disease by ... well, you already know. *Washington Post.com* 2005 Jan 11, pg HE01.

<http://www.washingtonpost.com/wp-dyn/articles/A64296-2005Jan10.html>



Adult Fitness ... OK, for all you “adults” with some competitive spirit still left, here are four basic measures of fitness that harkens back to your high school days. The four exercises are described so as to be standardized and a comparative chart is given to compare against fitness assessment in age categories. Go ahead, if you dare ...

Stoltz C. Fit for the Ages: No Matter How Old You Are, It's Time You Checked Your Performance Against These Fitness Yardsticks. *Washington Post.com* 2005 Jan 11, pg HE01.

<http://www.washingtonpost.com/wp-dyn/articles/A63962-2005Jan10.html>



Caffeine ... Then there is caffeine. A highly illustrated (with photographs) article on the current state of caffeine consumption worldwide as well as some history of the popular buzz. Did you know that a manufacturer of pantyhose has woven caffeine in the fibers as a method of weight loss?

Reid TR, Sacha B. Caffeine. *National Geographic* 2005 Jan;207(1):2-32.

Vocabulary ... Medication Reconciliation ... roughly defined as formal procedures to identify an accurate list of a patient's medications and compare it throughout the hospital stay, from admission, through procedures, to discharge. Medication errors in hospitals is a hot topic .. again. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is to require hospitals to adopt procedures that include a complete medication list (what a concept!). Also, medication reconciliation is one of the “best practices” of the Institute for Healthcare Improvement 100,000 lives campaign. The good news is that pharmacists are at least given a little credit for trying to emphasize the problem.

Landro L. Hospitals step up efforts to avoid medication errors. *Wall Street Journal online* 2005 Jan 12, pg. D4.

Naturally! ... Yet another incentive for pharmacists to learn more about natural products and herbals. California has joined 13 other states in licensing Naturopaths. Naturopathic medicine training is roughly similar to medical training for two years, then another two years is spent in natural healing, vitamins, herbs, etc and a holistic emphasis. In California, they will also have limited prescribing for “real” drugs. New York and Florida are considering the move as well.

MacGregor HE. With stethoscopes and nature's remedies. *Los Angeles Times.com* 2005 Jan 17.

<http://www.latimes.com/features/health/la-he-naturopath17jan17,1,989109.story?coll=la-headlines-health>

“Crack down” ... on methamphetamine labs, but the push will put the onus on pharmacists. Talk is heating up in many states of mandating that all products containing pseudoephedrine be more closely controlled. Due to the “epidemic” of meth labs and the attendant physical and social consequences, some states have made it similar to codeine and put it in a Schedule V category. Alabama certainly has its share of problems with it.

Simon S. States battling meth may put controls on cold pills. Los Angeles Times.com 2005 Jan 10.

<http://www.latimes.com/news/nationworld/nation/la-na-meth10jan10,0,6614839.story?coll=la-home-headlines>

The last “dose” ...

Despite all the recent admonitions to eschew our modern lifestyle and become more active, it is actually very dated advice:

The sovereign invigorator of the body is exercise, and of all exercises walking is the best.



--Thomas Jefferson [1743-1826]

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

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