

# AU InforMed

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## Key Inforbits

- One new drug and two new generics
- Herbals taking a pounding
- iPLEDGE ...
- New vaccine recommendations
- Ricin poisoning – review
- Self-regulation may have had its last chance

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

**New Drug** ... The FDA announced approval of **anidulafungin (Eraxis™)** by Pfizer Inc.) on February 21, 2006. Anidulafungin is an antifungal drug that is administered intravenously, and is used to treat *Candida* infections in the esophagus (candidiasis), blood stream (candidemia), and other forms of *Candida* infections, including abdominal abscesses and peritonitis (inflammation of the lining of the abdominal cavity). Anidulafungin was generally well tolerated in clinical studies. The most commonly reported adverse events were mild diarrhea, mild elevations in laboratory tests of liver enzymes, and headache; there were reports of serious hepatic abnormalities.

FDA. FDA approves new treatment for fungal infections. *FDA News* 2006 Feb 21.

<http://www.fda.gov/bbs/topics/news/2006/NEW01321.html>

**New Generic** ... A generic version of Coreg® has received tentative approval from the FDA. Generic **carvedilol** tablets will be available in 3.125mg, 6.25mg, 12.5mg and 25mg doses from Mylan Pharmaceuticals.

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&ApplNo=077316&SearchType=AddlSearch&SEARCHOPTION=B>

**New Generic** ... The FDA approved the first generic of **fluticasone propionate nasal spray** (innovator drug is Flonase® by GlaxoSmithKline) on February 22, 2006. Flonase® was first approved in 1994 and lost its final patent exclusivity in November 2005. It is used for treatment of nasal symptoms of seasonal and chronic allergic and nonallergic rhinitis, for adults and children ≥4 years old.

FDA. FDA approves first generic version of Flonase. *FDA News* 2006 Feb 22; P06-28.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01322.html>

**MedWatch** ... Bayer and FDA notified healthcare professionals of changes to the prescribing information for **nimodipine (Nimotop)**, including a boxed warning to notify prescribers about medication administration errors. Nimodipine is approved for oral administration to improve neurological outcome after subarachnoid hemorrhage. When administered intravenously or parenterally, it can cause serious adverse events, including death. Nimodipine must not be administered intravenously or by any parenteral route. Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare Professional letter and revised labeling, at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Nimotop>

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

**Natural ≠ effective ...** One of the arguments by the medical establishment against the use of herbal products has been the lack of controlled clinical trials showing effectiveness. Over the last few months, a number of trials have been published examining echinacea, saw palmetto, melatonin, fish oil, glucosamine and chondroitin. It looks as though the medical establishment may have a point! All of these trials have shown limited to no effectiveness; not a very good showing, but it likely won't dampen the enthusiasm of previous believers.

- Turner RB, Bauer R, Woelkart K, Hulsey TC, Gangemi JD. An evaluation of *echinacea angustifolia* in experimental rhinovirus infections. *N Engl J Med.* 2005 Jul 28;353(4):341-8.
- Bent S, Kane C, Shinohara K, Neuhaus J, Hudes ES, Goldberg H, et al. Saw palmetto for benign prostatic hyperplasia. *N Engl J Med.* 2006 Feb 9;354(6):557-66.
- Buscemi N, Vandermeer B, Hooton N, Pandya R, Tjosvold L, Hartling L, et al. Efficacy and safety of exogenous melatonin for secondary sleep disorders and sleep disorders accompanying sleep restriction: meta-analysis. *BMJ.* 2006 Feb 18;332(7538):385-393.
- MacLean CH, Newberry SJ, Mojica WA, Khanna P, Issa AM, Suttorp MJ, et al. Effects of omega-3 fatty acids on cancer risk: A systematic review. *JAMA.* 2006 Jan 25;295(4):403-15.
- Clegg DO, Reda DJ, Harris CL, Klein MA, O'Dell JR, et al. Glucosamine, chondroitin sulfate, and the two in combination for painful knee osteoarthritis. *N Engl J Med.* 2006 Feb 23;354(8):795-808.

**New flu vaccination guidelines for Health-Care Personnel ...** The Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) have issued new recommendations for healthcare personnel vaccination. The new guidelines apply to those in acute care hospitals, nursing homes, skilled nursing facilities, clinician's offices, urgent care centers, and outpatient clinics and to persons who provide home healthcare and emergency medical services. For more detail, go to:

Pearson ML, Bridges CB, Harper SA. Influenza vaccination of health-care personnel. *MMWR* 2006 Feb 24;55(RR-2):1-16.  
<http://www.cdc.gov/mmwr/pdf/rr/rr55e209.pdf>



**iPLEDGE program ...** is a strengthened risk management program to educate women about the risk of becoming pregnant while taking isotretinoin (Accutane<sup>®</sup> and its generics), a drug to treat severe recalcitrant nodular acne. It will be implemented on March 1, 2006, as planned. This comprehensive program seeks to reduce the risk of inadvertent pregnancy exposure by tightly linking negative pregnancy testing with dispensing of isotretinoin. Isotretinoin is a known and dangerous teratogen; it is also more recently associated with depression. Operational issues have been raised by dermatologists and pharmacists; the FDA, with sponsors and vendor, Covance Inc are working to assure a smooth administration. For questions about the iPLEDGE program contact iPLEDGE at 1-866-495-0654 or online at: <https://www.ipledgeprogram.com/>  
FDA and Manufacturers of Accutane and its Generics to Implement iPLEDGE Program on March 1, 2006. FDA Statement. Feb 23, 2006.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01324.html>

**Better than bleach ...** A paper presented at the American Society for Microbiology (ASM) Biodefense Research Meeting last week showed that the antimicrobial effectiveness of bleach could be greatly enhanced by adding white vinegar to the solution. Apparently at a more acidic pH, the hypochlorite form is much more prevalent and more effective in killing microbes. The authors recommend first diluting one cup of household bleach in one gallon of water and then adding one cup of white vinegar.

Vinegar increases the killing power of bleach. *Eureka Alert.* 2006 Feb 17.

[http://www.eurekaalert.org/pub\\_releases/2006-02/asfm-vik021306.php](http://www.eurekaalert.org/pub_releases/2006-02/asfm-vik021306.php)

**Ortho Evra® increases chance of clots?** ... Last week, Ortho-McNeil Pharmaceutical Inc., released preliminary data from two epidemiologic studies, conducted using large medical insurance claims databases in the United States. One of the studies showed a doubling in the risk of blood clots among users of the Ortho Evra® birth-control patch. The other study showed no increased risk when compared with women using a typical birth-control pill. This data has been shared with the FDA and is undergoing analysis.

Press Release. Results of two epidemiological studies provide important new clinical information about the safety of ORTHO EVRA®. Ortho-McNeil Pharmaceuticals Inc. 2006 Feb 16.

[http://www.orthoevra.com/html/pevr/newsroom\\_press\\_02162006.jsp?](http://www.orthoevra.com/html/pevr/newsroom_press_02162006.jsp?)



**New Recommendations for Tetanus, Diphtheria, and Pertussis** ... During spring 2005, two tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) products formulated for use in adolescents (and, for one product, use in adults) were licensed in the United States (BOOSTRIX®, GlaxoSmithKline Biologicals, Rixensart, Belgium [licensed May 3, 2005, for use in persons aged 10-18 years], and ADACEL™, Sanofi Pasteur, Toronto, Ontario, Canada [licensed June 10, 2005, for use in persons aged 11-64 years]). This statement, referenced below: 1) reviews tetanus, diphtheria and pertussis vaccination policy in the United States, with emphasis on adolescents; 2) describes the clinical features and epidemiology of pertussis among adolescents; 3) summarizes the immunogenicity, efficacy, and safety data of the two Tdap vaccines licensed for use among adolescents; and 4) presents recommendations for tetanus, diphtheria, and pertussis vaccination among adolescents aged 11-18 years.

Broder KR, Cortese MM, Iskander JK, Kretsinger K, Slade BA, Brown KH, et al. Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR*. 2006 Feb 23;55(early release):1-34.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e223a1.htm>



**Ricin Poisoning** ... For those of you who caught the news over the weekend, ricin was discovered in a roll of quarters used by a University of Texas student. Presence of ricin was confirmed, no one suffered ill effects and so far, no one seems to know from whence it came. There was a ricin scare a year or two ago, and it is considered a potential bioterror weapon. If you are interested, a nice review of ricin poisoning was published recently.

Associated Press. Texas student finds poison in coin roll. *New York Times.com* 2006 Feb 26.

[http://www.nytimes.com/2006/02/26/national/26ricin.html?\\_r=1&pagewanted=all&oref=slogin](http://www.nytimes.com/2006/02/26/national/26ricin.html?_r=1&pagewanted=all&oref=slogin)

Audi J, Belson M, Patel M, Schier J, Osterloh J. Ricin poisoning: A comprehensive review. *JAMA*. 2005 Nov 9;294(18):2342-2351.

### Reviews of Note ...

- Heres S, Davis J, Maino K, Jetzinger E, Kissling W, Leucht S. Why olanzapine beats risperidone, risperidone beats quetiapine, and quetiapine beats olanzapine: An exploratory analysis of head-to-head comparison studies of second-generation antipsychotics. *Am J Psychiatry*. 2006 Feb;163(2):185-94.
- Annual Over-the-Counter product survey. *Pharmacy Today*, OTC Supplement. American Pharmacists Association, 2006 Feb;12(2):6, 12, 19, 22, 22, 26.
- Felson DT. Osteoarthritis of the knee. *N Engl J Med* 2006 Feb 23;354(8):841-8.

## FROM THE LAY LITERATURE about medicine ...



**Self-regulation gone bad ...** There have been several articles over the last few months concerning the largess of the pharmaceutical companies to physicians and some groups have begun to offer “rules” for these interactions, including the industry itself (see *AU InforMed* 2006 Feb 1;4(4), and others.). It may be too late. For professions in particular, if they cannot effectively regulate themselves, the government will often step in and do it for them, and this seems to be happening now. Several states are looking into the interactions between the pharmaceutical industry and physicians with the intent of setting boundaries. At least nine states are considering such bills in their legislatures; Massachusetts is considering a bill that would ban all gifts to medical professionals. **Pharmacists** are included in these deliberations.

Appleby J. States want info about drugmaker’s gifts to doctors. *USA Today* 2006 Feb 17.

[http://www.usatoday.com/news/health/2006-02-16-doctor-gifts-usat\\_x.htm](http://www.usatoday.com/news/health/2006-02-16-doctor-gifts-usat_x.htm)

## NEW RESOURCES in the DILRC ...

- McEvoy GK, ed. *AHFS Drug Information 2006*. Bethesda, MD: American Society of Health System Pharmacists, 2006.
- *Physicians’ Desk Reference*. 60<sup>th</sup> ed. Montvale, NJ: Thomson PDR, 2006.
- *PDR for Nonprescription Drugs, Dietary Supplements, and Herbs: The Definitive Guide to OTC Medications*. 27<sup>th</sup> ed. Montvale, NJ: Thomson PDR, 2006.
- Brunton LL, Laxo JS, Parker KL, eds. *Goodman & Gilman’s The Pharmacological Basis of Therapeutics*. 11<sup>th</sup> ed. NY: McGraw-Hill, 2006.
- Glantz SA. *Primer on Biostatistics*. 6<sup>th</sup> ed. NY: McGraw-Hill, 2005.



## The last “dose” ...

### 10 worst presidential “errors”

A survey of presidential scholars, organized by the University of Louisville’s McConnell Center resulted in the “Top 10 Presidential Blunders.” Tops on the list was President James Buchanan who shoulders most of the blame for failing to avert the Civil War. President Bill Clinton came in at #10 for his poor judgment regarding a certain intern. To see the entire list, go to:

Scholars rate worst presidential errors. *USA Today* 2006 Feb 21.

[http://www.usatoday.com/news/washington/2006-02-18-presidential-goofs\\_x.htm](http://www.usatoday.com/news/washington/2006-02-18-presidential-goofs_x.htm)

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