

AU InforMed

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Key Inforbits

- New drug for fibromyalgia
- Off-label uses are big business
- NICE has a hard edge – coming to America?
- Generic drug use is up!
- Pharmacy is rated as a “Best Career”
- Gesundheit!

NEW DRUGS, and other related stuff ...

New Drug ... (1/14/2009) Forest Laboratories, Inc. (NYSE: FRX) and Cypress Bioscience, Inc. (Nasdaq: CYPB) today announced that **Savella™ (milnacipran HCl)**, a selective serotonin and norepinephrine dual reuptake inhibitor, was approved by the FDA for the **management of fibromyalgia**. The safety and efficacy of Savella™ was established in two US pivotal phase III clinical trials involving over 2,000 patients with fibromyalgia. The studies showed that Savella™ doses of 100 mg/day and 200 mg/day demonstrated statistically significant and clinically meaningful concurrent improvements in pain, patient global assessment, and physical function. The companies expect Savella™ to be available in pharmacies by March 2009. Savella™ will be marketed by Forest and its licensor, Cypress Bioscience. Pierre Fabre originally developed milnacipran and licensed the rights for North America to Cypress Bioscience.

<http://www.frx.com/news/PressRelease.aspx?ID=1244788> (Manufacturer press release)

MedWatch ... (12/31/2008) Celgene has issued a **Dear Healthcare Professional letter** describing a controlled clinical study suggesting that **Innohep may increase the risk for death**, compared to unfractionated heparin when used to treat elderly patients with renal insufficiency. It recommended consideration of alternatives to Innohep when treating these patients for deep vein thrombosis with or without pulmonary embolism.

Read the complete MedWatch 2008 Safety summary, including a link to the Dear Healthcare Professional letter and the December 2 FDA Ongoing Safety Review at:

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

MedWatch ... (1/13/2009) The FDA has provided updated information to its March 2008 Early Communication. The FDA is continuing to review clinical trial data to assess other **neuropsychiatric events, (mood and behavioral adverse events) related to drugs that act through the leukotriene pathway** (montelukast [Singular®], zafirlukast [Accolate®], zileuton [Zyflo®]). As a result, the FDA has not yet reached a conclusion regarding the clinical trial data on mood and behavioral adverse events associated with montelukast, zafirlukast, and zileuton.

Read the complete MedWatch Safety summary, including a link to the updated early communication and the original March 2008 communication at:

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

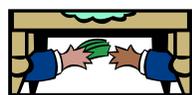
MedWatch ... (1/16/2009) The FDA issued a **public health advisory** to remind patients, healthcare professionals, and caregivers about potentially serious hazards of using skin numbing

products (**topical anesthetics**), for relieving pain from mammography and other medical tests and conditions. The FDA is concerned about the potential for these products to cause serious, life-threatening adverse effects, such as irregular heartbeat, seizures, breathing difficulties, coma and even death, when applied to a large area of skin or when the area of application is covered. The FDA is working with healthcare professional organizations and other media that distribute healthcare information to spread the message about the potential hazards and safe use of topical anesthetics. The Advisory and the Dear Colleague letter provide recommendations to both doctors and patients on safe use of these products.

Read the MedWatch 2009 safety summary, including links to the Public Health Advisory and "Dear Colleague" letter at: <http://www.fda.gov/medwatch/safety/2009/safety09.htm#Anesthetics>

FROM THE MEDICAL LITERATURE ...

Off-label prescribing – big business for a few drugs ... In a retrospective, cross-sectional study using commercial databases of prescribing information, a group analyzed drugs that were prescribed for off-label uses and assessed the quality of evidence supporting the non-FDA approved indications. From previous studies, 21% to 31% of prescriptions are for off-label uses, but this varies widely depending on drug class. In this study, the most common classes of drugs prescribed off-label were antidepressants, antipsychotics and anxiolytic-sedatives. The vast majority of off-label uses lacked sufficient evidence. The authors identified 14 drugs that merit high priority future research; quetiapine topped of most lists.



Walton SM, Schumock GT, Lee K-V, Alexander GC, Meltzer D, Stafford RS. Prioritizing future research on off-label prescribing: Results of a quantitative evaluation. *Pharmacotherapy*. 2008 Dec;28(12):1443-1452.

Fatal drug abuse characteristics ... In a population-based, observational study in West Virginia, records from medical examiners, prescription drug monitoring program and opiate treatment programs were examined and 295 decedents from unintentional pharmaceutical overdoses were identified. Some of the trends that came from the study included: 67% men; 92% aged 18 to 54 years; 63% of drugs were from diversion (21% from doctor-shopping); 93% of deaths involved opioid analgesics, but 79% of deaths involved more than one drug. Interestingly, as the age group increased the drug supply came more from doctor-shopping than drug diversion. Little of this is surprising, but here is the documentation.



Hall AJ, Logan JE, Toblin RL, Kaplan JA, Kraner JC, Bixler D, Crosby AE, Paulozzi LJ. Patterns of abuse among unintentional pharmaceutical overdose fatalities. *JAMA*. 2008 Dec 10;300(22):2613-2620.

Reviews of Note ...

- Abramowicz M, ed. Drugs for acne, rosacea and psoriasis. *Treatment Guidelines Med Lett*. 2008 Nov;6(75):75-82.
- Drummond MB, Dasenbrook ED, Pitz MW, Murphy DJ, Fan E. Inhaled corticosteroids in patients with stable chronic obstructive pulmonary disease: A systematic review and meta-analysis. *JAMA*. 2008 Nov 26;300(20):2407-2416.
- Abramowicz M, ed. Drugs for asthma. *Treatment Guidelines Med Lett*. 2008 Dec;6(76):83-90.

- Glezen WP. Prevention and treatment of seasonal influenza. *N Engl J Med*. 2008 Dec 11;359(24):2579-2585.
- Reddy M, Gill SS, Kalkar SR, Wu W, Anderson PJ, Rochon PA. Treatment of pressure ulcers: A systematic review. *JAMA*. 2008 Dec 10;300(22):2647-2662.

FROM THE LAY LITERATURE about medicine ...

NICE has a hard edge ... The National Institute for Health and Clinical Excellence (NICE) is a British government agency that in essence establishes a national formulary (at least, what it will pay for). Through complicated formulas a drug must demonstrate a cost-effectiveness to be approved by NICE. New (and typically very expensive drugs) get the attention. For instance, any drug that provides an extra six months of good-quality life for £10,000 or less is approved. Drugs that are more than about £18,000 for the same benefit are rarely approved. This is, of course, in response to escalating health care costs and in particular, drug costs. There has been much protest (a lot from pharmaceutical manufacturers, who have quietly been cutting prices to the U.K.), but many countries are taking note and adopting the approach. The U.S. which spends approximately double the average industrialized country on drugs may have to consider such a method.



Harris G. British balance benefit vs. cost of latest drugs. *New York Times*. December 3, 2008.

http://www.nytimes.com/2008/12/03/health/03nice.html?_r=1&ref=health

DSM-V will be a painful birth ... Interesting article about the upcoming major revision of one of psychiatry's staples, the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders, or DSM-V. Although at least three years away from publishing, there are already major disagreements and political maneuverings concerning what will and will not be included, and if included what it will be named. The last major revision was in 1994 and the last revision in 2000. Why the problem? According to a historian of psychiatry, Edward Shorter (no, not Tom Cruise), "In psychiatry no one knows the causes of anything, so classification can be driven by all sorts of factors" – political, social, and financial." It is so contentious that invited contributors must sign a nondisclosure agreement, and they must limit income from pharmaceutical manufacturers to less than \$10,000 per year. This appears to have some parallels to the making of sausage.



Carey B. Psychiatrists revise the book of human troubles. *New York Times*. December 18, 2008.

http://www.nytimes.com/2008/12/18/health/18psych.html?_r=1&ref=health

Fluoroquinolone tendinitis – who knew? ... Fluoroquinolone tendinitis is not a new phenomenon as it has been known for many years. Yet, due to increasing reports the FDA last year increased the visibility of the warning by requiring a "black box warning" and a medication guide be dispensed with the product. In addition to increasing reports, a big stimulus for the action was a lawsuit by a public action watch-dog committee, demanding more aggressive action by the FDA to inform the public. Fluoroquinolones are very commonly prescribed broad-spectrum antibiotics. One, Levaquin® (levofloxacin), is also known as "vitamin L" due to its popularity. The moral here for pharmacists is, do not be lulled into complacency about potential adverse effects. This is part of the counseling function, for patients and prescribers.



Young A. Some antibiotics overprescribed, effects not widely known. *Atlanta Journal-Constitution*, January 4, 2009.

http://www.ajc.com/news/content/metro/stories/2009/01/04/spotlight_antibiotics_0104_4dot_2DOT.html

Health care expenses still going up ... A new study has quantified figures for national health spending in 2007. The bad news is it's still going up; the good news is, not so fast. Health care spending now accounts for 16.2% of the gross domestic product or \$7421 for every person in the U.S. The same good news/bad news scenario applies to spending on drugs. Perhaps the biggest news for pharmacists is that **generic drug use is up** (67% in 2007 vs. 60% in 2005) and is given credit for the decreased rate of rise of this important category. Unfortunately, most of the figures given show increased spending in many categories.



Pearl R. Spending rise for health care and prescription drugs slows. New York Times. January 6, 2009.

<http://www.nytimes.com/2009/01/06/us/06healthcare.html?ref=health&pagewanted=print>

Update ...

Rx Pharmacy still a “Best Career” according to *U.S. News and World Report* ... A short review of pharmacy as a career, intended for students looking to choose a profession. They do a nice job of making it more interesting so that students will hopefully follow up with some of the links provided. There is much left out, but the intent is to be thumbnail. A good, unbiased information piece to give to prospective students.

Nemko M. Best Careers 2009: Pharmacist. U.S. News and World Report. 2009 Dec 11.

<http://www.usnews.com/articles/business/best-careers/2008/12/11/best-careers-2009-pharmacist.html>



The last “dose” ...

“Gesundheit”

Wishing people well after they sneeze is thought to have originated thousands of years ago. It was tied to the notion that a sneeze typically precedes illness.

- The Romans said, “Jupiter preserve you” or “Salve” which meant “good health to you.”
- The Greeks wished each other “long life.”
- Pope Gregory the Great coined the phrase “God bless you” during a bubonic plague epidemic in the 6th century.
- “Gesundheit” comes from Germany and means “health.”

Ancient superstitions held the sneeze to be dangerous. Some believed it caused the soul to escape the body through the nose. Saying “bless you” would stop the devil from claiming the person’s freed soul. Others believed the opposite; that evil spirits used the sneeze to enter a person’s body. There was also the misconception that the heart momentarily stops during a sneeze (it doesn’t), and that saying “bless you” was a way of welcoming the person back to life.”

[The Washington Post, Anatomy of a Sneeze and Cough. accessed 1/6/2009.

<http://www.washingtonpost.com/wp-srv/health/interactives/cold/> 1

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