

AU InforMed

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Key Inforbits

- TWO new drugs
- Unsafe natural products recalled
- DAWN indicates medicine cabinet dangerous
- Tamiflu causing behavioral problems?
- ADHD becoming a smoke screen?
- A history lesson

NEW DRUGS, and other related stuff ...

New Drug ... The FDA approved **lapatinib (Tykerb™)** by GlaxoSmithKline) on March 13, 2007. It is a new targeted anti-cancer treatment, to be used in combination with capecitabine (Xeloda®), for patients with advanced, metastatic breast cancer that is HER2 positive. The combination treatment is indicated for women who have received prior therapy with other cancer drugs. According to the American Cancer Society, about 180,000 new cases of breast cancer are diagnosed each year. Approximately 8,000 to 10,000 women die from metastatic HER2 positive breast cancer each year. Lapatinib is a kinase inhibitor working through multiple pathways (targets) to deprive tumor cells of signals needed to grow. Unlike, for example, trastuzumab — a monoclonal antibody, which is a large protein molecule that targets the part of the HER2 protein on the outside of the cell; lapatinib is a small molecule that enters the cell and blocks the function of this and other proteins. The most commonly reported side effects included diarrhea, nausea, vomiting, rash and hand-foot syndrome which may include numbness, tingling, redness, swelling and discomfort of hands and feet. Tykerb™ is available in tablets of 250 mg. An undivided dose of 1,250 mg should be taken orally once daily for 21 days and in combination with capecitabine on days 1-14 of a 21 day cycle.

FDA approves Tykerb for advanced breast cancer patients. *FDA News*. 2007 Mar 13; P07-44.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01586.html>

New Drug ... The FDA approved **eculizumab (Soliris™)** by Alexion Pharmaceuticals, Inc.), on March 16, 2007. It is the first product for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), a rare type of blood disorder that can lead to disability and premature death. Eculizumab is also classified as an Orphan Drug. PNH, which usually develops in adults, is a disease characterized by red blood cells that develop abnormally. Once the abnormal cells are present in the bloodstream, the complement system breaks these cells down which leads to abnormally darkened urine and causes anemia. Patients with PNH may have pain, fatigue and debilitating weakness, the need for frequent blood transfusions, blood clots, and life-threatening or fatal strokes, heart attacks and intestinal disease. Eculizumab does not cure PNH, but acts to block the complement system activity, including the destruction of PNH red blood cells. However, eculizumab's blockade of the body's natural immune system increases the patient's susceptibility to certain serious infections, particularly meningococcal infections that can cause bacterial meningitis. About one out of a million people will be diagnosed with PNH.

FDA approves first-of-a-kind drug to treat rare blood disorder. *FDA News*. 2007 Mar 16; P07-47.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01589.html>

MedWatch ... (3/14/2007). The FDA notified healthcare professionals and consumers of its request that **all manufacturers of sedative-hypnotic drug products, strengthen their product labeling** to include stronger language concerning potential risks including severe allergic reactions and complex sleep-related behaviors, which may include sleep-driving. FDA also requested that each product manufacturer send letters to health care providers to notify them about the new warnings, and that manufacturers develop patient Medication Guides for the products to inform consumers about risks and advise them of potential precautions to take. Read complete MedWatch 2007 Safety summary, including a link to the FDA press release, at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Sedative>

MedWatch ... (3/16 and 3/19/2007) Barodon SF, Cosmos Trading, Inc and the FDA notified consumers and healthcare professionals of a **voluntary nationwide recall of a supplement product sold under the name V.MAX, and Rhino Max (Rhino V Max)** in 5-tablet or 15-tablet boxes. Lab analysis by FDA found the product contains Aminotadalafil, an analogue of Tadalafil, an FDA-approved drug used to treat Erectile Dysfunction (ED). FDA advised that this poses a threat to consumers because Aminotadalafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Consumers who have V.MAX in their possession should stop using it immediately and contact their physician if they experienced any problem that may be related to the above. Read complete MedWatch 2007 Safety summary, including a link to the firm press release, at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#vmax> [V.MAX]
<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Rhino> [Rhino Max]

MedWatch ... (3/16/2007) The FDA notified healthcare professionals of new emerging **safety concerns about Zyvox** (linezolid) from a recent clinical study. This open-label, randomized trial compared linezolid to vancomycin, oxacillin, or dicloxacillin in the treatment of seriously ill patients with intravascular catheter-related bloodstream infections including those with catheter-site infections. Patients treated with linezolid had a higher chance of death than did patients treated with any comparator antibiotic, and the chance of death was related to the type of organism causing the infection. Patients with Gram positive infections had no difference in mortality according to their antibiotic treatment. In contrast, mortality was higher in patients treated with linezolid who were infected with Gram negative organisms alone, with both Gram positive and Gram negative organisms, or who had no infection when they entered the study. Linezolid is not approved for the treatment of catheter-related bloodstream infections, catheter-site infections, or for the treatment of infections caused by Gram negative bacteria. If infection with Gram negative bacteria is known or suspected, start appropriate therapy immediately. Read complete MedWatch 2007 Safety summary, including link to Drug Information Page, at: <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Zyvox>

FROM THE MEDICAL LITERATURE ...

DAWN Report ... A new report covering 2005 from the Drug Abuse Warning Network (DAWN) that monitors emergency department (ED) activity for drug-related admissions. The DAWN activity is part of the Substance Abuse and Mental Health Services Administration (SAMHSA). The big news from the report is the jump in numbers of overdoses involving prescription drugs. Benzodiazepines, prescription pain relievers, and methadone. Most of the cases involve multiple drugs and very commonly with alcohol. Of the 108 million ED visits in the U.S. 1.4 million were associated with drug misuse or abuse. Nearly one-half had some



component of prescription drug use, now rivaling the illicit drugs (eg, heroin, cocaine). The 94-page report is full of more specific information.

Drug abuse warning network, 2005: National estimates of drug-related emergency department visits. U.S.

Department of Health and Human Services. Substance abuse and Mental Health Services Administration.

<https://dawninfo.samhsa.gov/pubs/edpubs/default.asp>

From the Office of National Drug Control Policy: Proper Disposal of Prescription Drugs Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so.
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.



A PDF version is at this site.

http://www.whitehousedrugpolicy.gov/drugfact/factsht/proper_disposal.html

Reviews of Note ...

- Simpson D, McCormack PL, Keating GM, Lyseng-Williamson KA. Insulin lispro: A review of its use in the management of diabetes mellitus. *Drugs*. 2007;67(3):407-434.
- Neubauer S. The failing heart – An engine out of fuel. *N Engl J Med*. 2007 Mar 15;356(11):1140-1151.
- Dubé C, Rostom A, Lewin G, Tsertsvadze A, Barrowman N, Code C, et al. The use of aspirin for primary prevention of colorectal cancer: A systematic review prepared for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2007 Mar 6;146(5):365-375.
- Rostom A, Dubé C, Sewin G, Tsertsvadze A, Barrowman N, Code C, et al. Nonsteroidal anti-inflammatory drugs and cyclooxygenase-2 inhibitors for primary prevention of colorectal cancer: A systematic review prepared for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2007 Mar 6;146(5):376-389.

FROM THE LAY LITERATURE about medicine ...

Tamiflu[®]-induced delirium ... A report from Japan warns about bizarre behavior in teenagers taking Tamiflu[®] (oseltamivir by Roche). Reports include teens jumping from balconies or running into traffic. Such warnings are already included in the U.S. package labeling, largely from Japanese reports. There is no clear cause/effect relationship as such behavior may also be caused by influenza infection.

Pollack A. Japanese officials issue warning on flu drug. *New York Times*. 2007 Mar 21.

http://www.nytimes.com/2007/03/21/world/asia/21tamiflu.html?_r=1&ref=health&oref=slogin

Second time around the track? ... Off-label uses are common practice, but this one seems like a colorized version of a black-and-white movie. Pediatricians are prescribing drugs indicated for attention deficit hyperactivity disorder (ADHD) as weight loss drugs, albeit in a very “under-the-counter” fashion. In particular, Adderall® is mentioned in the article, which happens to be a mixed salt amphetamine. Amphetamines were commonly prescribed decades ago and hailed as wonderful therapy, until the down side of the drug began to become apparent. They are effective and this has apparently been rediscovered in our overweight teenagers. The age-old question, which is worse ...

Cohen E. ADHD drug use for youth obesity raises ethical questions. *CNN.com* 2007 Mar 21. <http://www.cnn.com/2007/HEALTH/03/21/vs.adderall/index.html>

Vaccine makers pricing themselves out of the market ... There are beginnings of a vaccine revolt, particularly in pediatrician’s offices across the country. The number of recommended vaccines for infants/children keeps rising and the pediatrician is on the front line for administration. The big issue is reimbursement for increasingly expensive vaccines and the investment needed to stock supplies. Also, insurers are often reluctant to reimburse, or reimburse fully. A couple of the most recent, expensive vaccines are Gardasil® (\$360 for 3 injections) and RotaTeq® (\$190). Some physicians are writing prescriptions for the vaccines, which the patient takes to the pharmacy to fill (they have to order it), and then return to the physician office for administration. In 1980 the recommended vaccinations included seven injections and four oral doses, for \$59. Today it is 37 injections and 3 oral doses for \$1600. Who thinks a form of socialized medicine and/or price controls are coming?

Pollack A. Pediatricians voice anger over costs of vaccines. *New York Times*. 2007 Mar 24.

http://www.nytimes.com/2007/03/24/business/24-vaccine.html?_r=1&ref=health&oref=slogin

AUBURN HSOP FACULTY in the literature ...

- Lloyd KB, Berger BA. Communication concerning sensitive issues: Coronary heart disease. *U.S. Pharmacist*. 2007 Feb;32(2):80-2,85.
- Gordon A. Spray or shot: flu vaccine’s non-needle nasal option. *Auburn Plainsman*. 2007 Mar 22;113(25):B1. [Dr.’s **Michael Reinke and Pamela Stamm** interviewed for information on the nasal flu vaccine.]



The last “dose” ...

“Those who cannot remember the past are condemned to repeat it. “

-- George Santayana (1863–1952), U.S. philosopher, poet.
Life of Reason, 'Reason in Common Sense,' ch. 12 (1905-6).

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

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