

# AU InforMed

Volume 5 Number 30 (Issue 165)

Friday, September 7, 2007



## Key Inforbits

- 2 new drugs, Somatuline and Evithrom
- New smallpox vaccine??
- The Fat survey, Alabama included
- New Asthma guidelines released
- Physicians and patients and ADRs
- Battle of the bedsore – real reason?

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

**New Drug** ... (8/30/2007) The FDA has approved **lanreotide acetate injection (Somatuline Depot)** by Beaufour Ipsen, Paris, France) for the treatment of **acromegaly**, a rare and potentially life threatening disease in adults caused by abnormal secretion of growth hormone (GH), commonly from a benign tumor located in the pituitary gland located in the brain. The FDA has approved Somatuline Depot for the long-term treatment of patients with acromegaly who have had inadequate response to or can not be treated with surgery and/or radiation therapy. Common side effects include diarrhea, gallstones, itching, bradycardia, and change in blood sugar levels. The FDA designated Somatuline Depot orphan status. Acromegaly affects approximately 15,000 people in the United States and Canada and is most commonly found in middle-aged adults. Patients with acromegaly have reduction in life expectancy of 5 to 10 years.

FDA approves new drug to treat rare disease, acromegaly. *FDA News*. 2007 Aug 30.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01692.html>

**New Drug** ... (8/28/2007) The FDA approved **Evithrom™ (human thrombin)**, manufactured by Omrix Biopharmaceuticals, Ltd., Ramat Gan, Israel, distributed by Johnson & Johnson Wound Management), a blood-clotting protein used to help control bleeding during surgery. Evithrom™ is the first human thrombin approved since 1954 and is the only product currently licensed. It is derived from human plasma obtained from carefully screened and tested U.S. donors and has undergone steps to further reduce the risk for transfusion-transmitted diseases. It is indicated as an aid to stop oozing and minor bleeding from capillaries and small veins and when control of bleeding by standard surgical techniques is ineffective or impractical. The product is applied to the surface of bleeding tissue; it must not be injected into blood vessels.

FDA Approves Human Thrombin for Topical Use in Surgery. *FDA News*. 2007 Aug 28.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01690.html>

**New vaccine** ... (9/1/2007) The FDA has licensed a **new vaccine to protect against smallpox**. The vaccine, ACAM2000 (by Acambis Inc. of Cambridge, England and Cambridge, Mass), is intended for the inoculation of people at high risk of exposure to smallpox and could be used to protect individuals and populations during a bioterrorist attack. A worldwide vaccination program eradicated smallpox in the population. The last case of naturally occurring smallpox in the U.S. was in 1949 and the last case in the world was reported in Somalia in 1977. The symptoms of smallpox typically began with high fever, head and body aches. A rash followed which spread and progressed to raised bumps and pus-filled blisters that crusted, scabbed, and

fell off after about three weeks, leaving a pitted scar. The fatality rate historically was about 30 percent. ACAM2000 is made using a pox virus, vaccinia, which is related to the smallpox virus. The vaccine contains live vaccinia virus; it causes a mild infection that stimulates an immune response that effectively protects against smallpox without actually causing the disease.

FDA approves second-generation smallpox vaccine. *FDA News*. 2007 Sep 1.

<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01693.html>

**New Indication** ... (8/17/2007) **Zoledronic acid (Reclast<sup>®</sup> by Novartis) Injection** has been approved by the FDA as the first and only once-yearly medicine for **postmenopausal osteoporosis**. Reclast<sup>®</sup> is given as a once-yearly 15-minute intravenous (IV) infusion.

Reclast<sup>®</sup>/Aclasta<sup>®</sup> is approved in more than 60 countries, including the US, Canada and the EU for the treatment of Paget's disease, the second most common metabolic bone disorder.

Additional studies are ongoing to examine the use of Reclast<sup>®</sup> to prevent fractures following a hip fracture in men and women, treatment of corticosteroid-induced osteoporosis, and male osteoporosis. Zoledronic acid is also available in a different dosage under the brand name Zometa<sup>®</sup> Injection for use in certain oncology indications.

<http://www.pharma.us.novartis.com/newsroom/pressReleases/releaseDetail.jsp?PRID=2029>

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

**F as in FAT** ... The newest survey telling us what we already knew. Adult obesity rates rose in 31 states over the year; 22 states increased for two years in a row, and perhaps tellingly, no state showed a decrease. The South and Southeast are heaviest and Mississippi weighs in at #1 with over 30% of its population obese. Alabama is #3 with 29.4% of its population obese; Alabama ranks #11 for overweight youths (ages 10-17). The "healthiest" state for adults was Colorado and Utah for youths. Alabama is worse than the national average for participation in physical exercise, but the state is in the minority for requiring nutritional standards for school food and limit the sale of unhealthy food on school property (vending machines, bake sales, etc).

Levi J, Gadola E, Segal LM. F as in Fat: How obesity policies are failing in America, 2007. Washington, DC: Trust for America's Health, 2007. <http://healthyamericans.org/>

<http://healthyamericans.org/reports/obesity2007/Obesity2007Report.pdf> [Full report, 120 pp.]

**Can't we all just get along** ... A World Health Organization (WHO) report is emphasizing the international spread of disease as a public health security risk, and focuses on ways to try to combat the spread. The primary message is that **sharing information among nations** is the only way such security can be achieved. In addition to sharing information about surveillance and outbreaks of disease, also sharing of technologies, materials, training, laboratory capacity, etc is essential to cooperation. Very recent examples of potential problems include a patient with suspected resistant tuberculosis who flew to many countries without questions due to agencies lagging behind in notification, and the difficulty of convincing some southeast Asian countries to share samples of bird flu virus due to fear of missing out on lucrative vaccine licensing opportunities. According to the report, since 1967 there have been at least 39 new pathogens identified including HIV, Ebola hemorrhagic fever, Marburg fever and SARS. Additionally, old diseases that are straining to reemerge such as pandemic flu, tuberculosis and malaria.

Prentice T, ed. International spread of disease threatens public health security: The world health report 2007 focuses on building a safer future. <http://www.who.int/mediacentre/news/releases/2007/pr44/en/print.html>

The World Health Report 2007: A Safer Future: Global Public Health Security in the 21<sup>st</sup> Century. Geneva: World Health Organization, 2007.

**New Guidelines ... Diagnosis and Management of Asthma ...** Newly revised national treatment guidelines for asthma have been released from the National Heart, Lung, and Blood Institute. These were last updated in 2002 and among other things, the new guidelines recognize that children 5-11 years of age have different treatment needs than other age groups. The guidelines also contain new recommendations on the use of leukotriene receptor antagonists and emphasize the use of inhaled corticosteroids to control asthma. The complete 440 page report is available at the web site below.

Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. National Asthma Education and Prevention Program. National Heart, Lung, and Blood Institute. 2007.

<http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm>

**Physicians dismissive of patient ADR complaints ...** 650 patients with self-reported adverse drug reactions (ADR) while on a “statin” were recruited through standard advertising means (Internet, newspaper, TV) in the San Diego, CA area. They completed a survey designed to elicit information on patient characteristics, drug dose, ADR character, time course of ADR and quality-of-life. The questionnaire centered around literature-supported statin-related ADRs and the interactions with their physicians concerning the patient’s perceived ADRs. The patient most commonly initiated the discussion (86% to 98%, depending on symptom). Once initiated, physicians endorsed the possibility of a symptom-drug connection 19% to 39% of the time. There are significant limitations to a study of this type, but the results are being widely reported in the lay press.

Golomb BA, McGraw JJ, Evans MA, Dimsdale JE. Physician response to patient reports of adverse drug effects: Implications for patient-targeted adverse effect surveillance. *Drug Safety*. 2007;30(8):669-675.

<http://drugsafety.adisonline.com/pt/re/drs/abstract.00002018-200730080-00003.htm;jsessionid=GJtW1ZWY8Mrgmh57ZkjQGgmy6HrKZFsnQpJmQFnpsgFZ6TQjLNGV!-79285651!181195629!8091!-1>

### **Reviews of Note ...**

- Abramowicz M, ed. Drugs for sexually transmitted infections. *Med Lett Treat Guidelines*. 2007 Sep;5(61):81-88.
- Singh M, Holmes DR Jr. Acute myocardial infarction. *Med Clin N Am*. 2007 Jul;91(4):537-803. (14 articles)
- Brunzell JD. Hypertriglyceridemia. *N Engl J Med*. 2007 Sep 6;357(10):1009-1017.
- Kroon LA. Drug interactions with smoking. *Am J Health-Syst Pharm*. 2007 Sep 15;64:1917-1921.

### **FROM THE LAY LITERATURE about medicine ...**

**“Urgent Care Lite” ...** a moniker for the “drugstore clinics” that are popping up all over the country. These clinics began 2-3 years ago, generally staffed with nurse practitioners or physician assistants, typically located in large retail pharmacy chains (eg, Wal-Mart, CVS, Walgreens), and treat minor illnesses such as allergies, minor infectious diseases or injury, and sore throat. They are seen as a particular boon to the uninsured because they are generally cheaper than a physician visit and have a shorter wait. However, many insured patients with a family physician frequent them too, primarily for convenience. Many of these cases may previously have been seen in an emergency department where expenses would be dramatically higher. A number of physician groups are strongly opposed to these clinics, citing lack of

continuity of care and potential for inappropriate treatment. Enough noise has been generated that regulators may be treating these clinics with increased scrutiny.

Kershaw S. Drugstore clinics spread, and scrutiny grows. *New York Times*. 2007 Aug 23.

[http://www.nytimes.com/2007/08/23/nyregion/23clinic.html?\\_r=1&ref=health&oref=slogin](http://www.nytimes.com/2007/08/23/nyregion/23clinic.html?_r=1&ref=health&oref=slogin)

**Battle of the Bed sore ... but the real issue is, why now ...** An article that describes several institution's approach to combating bed sore, or pressure ulcer, development and treatment. It appears that significant progress is being made against this stubbornly resistant enemy of the bedridden many of whom are elderly. For an example of its dangers, a precipitating cause for Christopher Reeve's death may have been a pressure ulcer. The real issue however, is the motivation for this progress. The Centers of Medicare and Medicaid Services (CMS) announced that as of October 2008, it will no longer reimburse hospitals for treating eight "reasonably preventable" conditions, one of which is pressure ulcers. Now, almost magically, institutions are bringing a concerted effort against this painful, dangerous and sometimes deadly condition. This should make even the most die-hard capitalists pause.

Landro L. The Informed Patient. Hospitals combat dangerous bedsores: New Medicare payment rules spur push for prevention; the 'four-eyed body check.' *Wall Street Journal*. 2007 Sep 5; p. D1.

### **AUBURN HSOP FACULTY and STUDENTS in the literature ...**

- Gosa B, Walker PD. Common nutritional supplements used to enhance athletic performance. *US Pharm*. 2007 Aug;32(8):55-61.

### **NEW RESOURCES in the DILRC ...**

- Harvey RA, Champe PC, eds. Harvey RA, Champe PC, Fisher BD. *Lippincott's Illustrated Reviews: Microbiology*. 2<sup>nd</sup> ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer, 2007.
- Harvey RA, Champe PC, eds. Howland RD, Mycek MJ. *Lippincott's Illustrated Reviews: Pharmacology*. 3<sup>rd</sup> ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer, 2006.
- Harvey RA, Champe PC, eds. Champe PC, Harvey RA, Ferrier DR. *Lippincott's Illustrated Reviews: Biochemistry*. 3<sup>rd</sup> ed. Baltimore: Lippincott Williams & Wilkins/Wolters Kluwer, 2005.



### **The last "dose" ...**

Infectious diseases introduced with Europeans, like smallpox and measles, spread from one Indian tribe to another, far in advance of Europeans themselves, and killed an estimated 95% of the New World's Indian population.

Jared Diamond, American Scientist and author [1937 - ]

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