AU InforMed

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Key Inforbits

- 5 new drugs and a new aspirin form
- Prepared for the coming **Zombie** apocalypse!?
- Would Zombies be affected by Bath Salts?
- Measles are real and coming back?
- The polypill prevents what could ail you.
- Thanks to our soldiers!

NEW DRUGS, and other related stuff …

New Drug … (5/13/2011) The FDA has approved **boceprevir (Victrelis™** by Merck) to treat certain adults with chronic hepatitis C. Boceprevir is used for patients who still have some liver function, and who either have not been previously treated with drug therapy for their hepatitis C or who have failed such treatment. Victrelis™ is approved for use in combination with peginterferon alfa and ribavirin. Victrelis™ is taken three times daily with food. Boceprevir is a protease inhibitor, which work by binding to the virus and preventing it from multiplying. The most commonly reported side effects, in combination with pegylated interferon and ribavirin, include fatigue, anemia, nausea, headache and dysgeusia. Sustained virologic response can result in decreased cirrhosis and complications of liver disease, decreased rates of liver cancer (hepatocelluar carcinoma), and decreased mortality.

FDA approves Victrelis for Hepatitis C. FDA News Release. 2011 May 13.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm255390.htm

New Drug … (5/20/2011) The FDA has approved **rilpivirine (Edurant™** manufactured by Tibotec Therapeutics in Raritan, NJ, a division of Centocor Ortho Biotech Inc.) in combination with other antiretroviral drugs for the treatment of HIV-1 infection in adults who are treatment-naïve. Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI), thus blocking HIV viral replication. It is to be used as part of a highly active antiretroviral therapy (HAART) regimen. Edurant™ is taken once a day with food. Rilpivirine was shown as effective as efavirenz in lowering viral load. The most commonly reported side effects with rilpivirine included depression, insomnia, headache and rash. Fewer patients stopped taking the drug due to side effects as compared to patients taking efavirenz.

FDA approves new HIV treatment. FDA News Release. 2011 May 20.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm256087.htm

New Drug … (5/23/2011) The FDA has approved **telaprevir (Incivek™** by Vertex Pharmaceuticals of Cambridge, MA), a protease inhibitor, to treat adults with chronic hepatitis C infection with interferon therapy made up of peginterferon alfa and ribavirin. Incivek™ is used for patients who have either not received interferon-based drug therapy for their infection or who have not responded adequately to prior therapies. Incivek™ is a pill taken three times a day with food. Most people with a good early response to the combination regimen can be treated for 24 weeks rather than the recommended 48 weeks of treatment with the standard of care. The most

commonly reported side effects in patients receiving telaprevir in combination with peginterferon alfa and ribavirin include rash, low red blood cell count (anemia), nausea, fatigue, headache, diarrhea, itching (pruritus), and anal or rectal irritation and pain. Rash can be serious and can require stopping telaprevir or all three drugs in the treatment regimen.
FDA approves Incivek for hepatitis C. FDA News Release. 2011 May 23.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm256299.htm
http://www.incivek.com/ (Vertex package insert)

New Drug … (5/27/2011) The FDA has approved **fidaxomicin (Dificid™** by Optimer Pharmaceuticals Inc., San Diego, CA) tablets for the treatment of *Clostridium difficile*-associated diarrhea (CDAD). *Clostridium difficile* (*C. difficile*) is a bacterium that can cause diarrhea and lead to serious intestinal conditions, including death in severe cases. The safety and efficacy of fidaxomicin were demonstrated in two trials that included 564 patients with CDAD that compared fidaxomicin with vancomycin. Fidaxomicin is a macrolide antibiotic to be taken two times a day for 10 days, with or without food. The most common side effects reported with fidaxomicin included nausea, vomiting, headache, abdominal pain, and diarrhea. The most effective way to prevent CDAD is thorough handwashing with soap and warm water.
FDA approves treatment for Clostridium difficile infection. FDA News Release. 2011 May 27.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm257024.htm

New Treatment … (5/27/2011) The FDA has approved **Solesta®** by Oceana Therapeutics Inc., Edison, N.J.) a sterile, injectable gel bulking agent comprised of dextranomer microspheres and sodium hyaluronate, to treat fecal incontinence in patients for whom other therapies such as diet change, fiber therapy or anti-motility medications failed. The Solesta® gel is injected into a layer of tissue beneath the anus lining and may help build tissue in that area. By growing the surrounding tissue, the opening of the anus narrows and the patient may be able to better control those muscles. Solesta® is approved for use in patients ages 18 and up and there are numerous contraindications to its use. The most common side effects included injection area pain and bleeding. Infection and inflammation of anal tissue are more serious risks, but are less common.
FDA approves injectable gel to treat fecal incontinence. FDA News Release. 2011 May 27.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm257112.htm
Sponsor Summary for Solesta® P100014. Center for Devices and Radiological Health (CDRH) Advisory Panel. Oceana Therapeutics Inc. 2010 Dec 2. (65 pages)
http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/medicaldevices/medicaldevicesadvisorycommittee/gastroenterology-urologydevicespanel/ucm235143.pdf

New Dose Form … (5/23/2011) **Bayer® aspirin** is now available in a **quick-release** formulation, using a Pro-Release™ technology that utilizes much smaller particles that aid in drug absorption. The effect is that pain is relieved twice as fast as the regular version, according to the manufacturer. It is up to further study as to whether this is a "clinically significant" difference or if gastrointestinal bleeding is affected. Bayer® aspirin was first released in 1899.
Bayer healthcare launches the next generation of aspirin for pain relief - clinically proven to relieve pain twice as fast as before. PRNewswire. 2011 may 23. http://multivu.prnewswire.com/mnr/bayer/50414/

FROM THE MEDICAL LITERATURE …

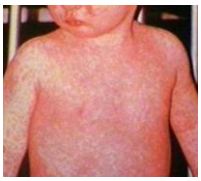
Social Media: Preparedness 101: Zombie Apocalypse … just in case you missed it! The Centers for Disease Control and Prevention (CDC) has come up with a creative way of

informing the public about disaster preparedness. In addition to a zombie invasion, the CDC provides information about more mundane disasters such as weather (tornado's, hurricanes, etc) and pandemics. The CDC also assures the public that they are fully prepared for a zombie outbreak and will respond to investigate as with any disease outbreak. Who says the government doesn't have a sense of humor?!?
http://emergency.cdc.gov/socialmedia/zombies_blog.asp

"Bath Salts" characterized … Based on a sudden increased incidence of emergency department (ED) visits in January/February 2011, the Michigan Department of Community Health worked with the Children's hospital of Michigan Poison Control Center to characterize the toxicities of "bath salts." In 2½ months 35 people were identified who had ingested, inhaled or injected "bath salts." These compounds generally contain stimulant chemicals such as 3,4-methylenedioxypyrovalerone (MDPV) or 4-methylmethcathinone (mephedrone). The most prevalent age group was 20-29 years, most commonly injected and often other drugs were present. The most common symptoms were agitation, tachycardia, delusions/hallucinations and seizure/tremor. One person was dead upon arrival to the ED and 17 required hospitalization. These compounds are generally sold in convenience stores, gas stations, etc under a wide variety of trade names, and are commonly labeled as 'not for human consumption.' **CAVEAT EMPTOR!**

Emergency department visits after use of a drug sold as "Bath Salts" – Michigan, November 13, 2010-March 31, 2011. MMWR. 2011 May 20;60:624-627. http://www.cdc.gov/mmwr/PDF/wk/mm6019.pdf

Measles outbreak – it's not over until it's over … Measles is a highly contagious, acute viral illness that can lead to serious complications and death. Endemic or sustained measles transmission has not occurred in the U.S. since the late 1990s, despite importations. During 2001 to 2008, a median of 56 (range: 37 to 140) measles cases were reported to the CDC annually; **during the first 19 weeks of 2011, 118 cases of measles were reported**, the highest number in this period since 1996. Of the 118 cases, 105 (89%) were associated with importation from other countries. MMR vaccine is recommended routinely for all children at age 12 to 15 months, with a second dose at age 4 to 6 years. Adult vaccination schedules also exist. Measles is endemic in many countries, and exposures might occur in airports and in countries of travel. People at home may also be exposed to returning travelers who have contracted measles. All travelers aged ≥6 months are eligible to receive MMR vaccine and should be vaccinated before travel. **Maintaining high immunization rates with MMR vaccine is the cornerstone of outbreak prevention**.



Measles – United States, January-May 20, 2011. MMWR. 2011 May 24;60:1-4 (early release).
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm60e0524a1.htm?s_cid=mm60e0524a1_w

"Polypill" alive and well … Hope springs eternal for a magic pill that will prevent many of the self-induced ills that generally manifest in our later decades. The latest version is a 4-drug combination of aspirin 75 mg, lisinopril 10 mg, hydrochlorothiazide 12.5 mg and simvastatin 20 mg; various other versions have been proposed, some 5-drug combinations. It was given in double-blind, randomized fashion with placebo control to 378 patients without indication for any component but with a 5-year cardiovascular risk of >7.5%. The findings showed reductions of systolic blood pressure and LDL-cholesterol but also an ADR rate of about 17%. Not bad odds in a high risk group.

PILL Collaborative Group (2011) An international randomised placebo-controlled trial of a four-component combination pill ("Polypill") in people with raised cardiovascular risk. PLoS ONE 2011 May;6(5): e19857. doi:10.1371/journal.pone.0019857
http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0019857

Reviews of Note …

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NEW RESOURCES in the DIC …

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The last "dose" …

We come, not to mourn our dead soldiers, but to praise them.
~Francis A. Walker [1840 – 1897]

An electronic bulletin of drug and health-related news highlights, a service of …
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• Phone 334-844-4400 • Fax 334-844-8366 • http://www.pharmacy.auburn.edu/dilrc/dilrc.htm
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