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Significant New Drugs and Biologics for 2010:

| Generic Name | Brand Name | Classification/Use | Manufacturer |
|--|---|--|-------------------------------|
| Alcaftadine | <i>Lastacaft</i> | Antihistamine, ophthalmic | Vistakon Pharmaceutical |
| Alglucosidase Alfa | <i>Lumizyme</i> | Pompe Disease | Genzyme |
| Alpha ₁ -Proteinase Inhibitor | <i>Glassia</i> | For alpha ₁ -proteinase inhibitor replacement | Kamada |
| Cabazitaxel | <i>Jevtana</i> | Cancer Agent | Sanofi-Aventis |
| Carglumic Acid | <i>Carbaglu</i> | Hyperammonemia | Orphan Europe |
| Ceftaroline Fosamil | <i>Teflaro</i> | Cephalosporin (IV) | Forest Labs |
| Collagenase Clostridium Hystolyticum | <i>Xiaflex</i> | Dupuytren's contracture | Auxilium Pharmaceuticals |
| Dabigatran Etextilate Mesylate | <i>Pradaxa</i> | Direct thrombin inhibitor anticoagulant | Boehringer Ingelheim |
| Dalfampridine | <i>Ampyra</i> | Multiple sclerosis | Acorda Therapeutics |
| Denosumab | <i>Prolia</i> <i>Xgeva</i> (concentrate) | Osteoporosis Bone Metastases | Amgen |
| Dienogest/Estradiol Valerate | <i>Natazia</i> | 4-phasic Oral Contraceptive | Bayer |
| Ecallantide | <i>Kalbitor</i> | Hereditary Angioedema | Dyax |
| Eribulin Mesylate | <i>Halaven</i> | Cancer Agent | Eisai |
| Everolimus | <i>Zortress</i> | Immunosuppressant | Novartis |
| Fingolimod HCl | <i>Gilenya</i> | Multiple Sclerosis | Novartis |
| Hexaminolevulinate HCl | <i>Cysview</i> | Imaging Agent for Bladder Cancer | GE Healthcare/ Photocure ASA |
| Incobotulinumtoxin A | <i>Xeomin</i> | Cervical Dystonia | Merz |
| Liraglutide | <i>Victoza</i> | Diabetes | Novo Nordisk |
| Lurasidone | <i>Latuda</i> | Atypical Antipsychotic | Sunovion Pharmaceuticals |
| Pegloticase | <i>Krystexxa</i> | Gout | Savient |
| Pitavastatin Calcium | <i>Livalo</i> | Statin for hypercholesterolemia | Kowa; Lilly |
| Polidocanol | <i>Asclera</i> | Sclerosing agent | BioForm Medical |
| Romidepsin | <i>Istodax</i> | Cancer Agent | Gloucester |
| Sipuleucel-T | <i>Provenge</i> | Cancer Agent | Dendreon |
| Tesamorelin | <i>Egrifta</i> | HIV-associated lipodystrophy | EMD Serono/ Theratechnologies |
| Tocilizumab | <i>Actemra</i> | Arthritis | Genentech |
| Ulipristal Acetate | <i>ella</i> | Emergency Oral Contraceptive | Watson |
| Velaglucerase Alfa | <i>VPRIV</i> | Gaucher Disease | Shire |

Hussar DA. Pharmacist Activist. 2010 Dec;5(12):2. Pharmacist's Letter 2010. Traynor K. Am J Health-Syst Pharm. 2011 Feb 1;68:187-9.

NEW DRUGS, and other related stuff ...

New Orphan Drug ... (1/4/2011) Optimer Pharmaceuticals, Inc. has announced that **fidaxomicin**, the company's lead product candidate, has been granted orphan drug designation from the FDA for the treatment of pediatric *Clostridium difficile* infection in children 16 years of age or younger. A New Drug Application (NDA) has also been filed with the FDA. The FDA



Orphan Drug Designation is intended to support the clinical development of drugs for diseases and conditions that affect fewer than 200,000 people in the US. Orphan Drug Designation gives seven years of market exclusivity for the designated indication in the U.S. from the date the product receives marketing approval for that indication, among other benefits to the sponsoring company. This designation does not imply that fidaxomicin has demonstrated the efficacy, safety and quality required for drug approval in the U.S.

Optimer Pharmaceuticals Receives Orphan Drug Designation for Fidaxomicin for the Treatment of Pediatric *Clostridium difficile* Infection. San Diego, CA: Optimer Pharmaceuticals, Inc. Press Release. 2011 Jan 4. Available at: http://www.optimerpharma.com/news.asp?news_story=141&page_num=&year=2011

New Drug ... (1/18/2011) The FDA has approved **spinosad (Natroba™)** by ParaPRO LLC of Carmel, Ind.), a Topical Suspension 0.9% for the treatment of head lice infestation in patients ages 4 years and older. Natroba™ is a topical drug product and should be applied only to the child's scalp or hair. Common adverse events reported include redness or irritation of the eyes and skin. Safety in pediatric patients below the age of 4 years has not been established. Although Natroba™ is not approved for use in children younger than 4 years, it is especially important not to use in infants because the product contains benzyl alcohol.

FDA approves head lice treatment for children and adults. FDA Press Release. Jan 18, 2011.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240302.htm>

New Drug ... (1/21/2011) The FDA has approved **vilazodone hydrochloride (Viibryd™)** tablets by PGxHealth, New Haven, Conn.) to treat major depressive disorder in adults. The most frequent adverse reactions reported by patients taking Viibryd™ in clinical trials included diarrhea, nausea, vomiting, and insomnia. Viibryd™ and all other antidepressant drugs have a boxed warning and a patient medication guide describing the increased risk of suicidal thinking and behavior in children, adolescents, and young adults ages 18 to 24 during initial treatment. Depression and other serious psychiatric disorders themselves are the most important causes of suicide and close monitoring of patients starting these medications is necessary.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240642.htm> (Press Release)

http://www.viibryd.com/NDA_22_567_012111.pdf (Package Insert)

New Indication ... (12/22/2010) The FDA has approved the vaccine **Gardasil®** ([Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] by Merck and Co) for the prevention of anal cancer and associated precancerous lesions due to human papillomavirus (HPV) types 6, 11, 16, and 18 in people ages 9 through 26 years. Gardasil® is already approved for the same age population for the prevention of cervical, vulvar, and vaginal cancer and the associated precancerous lesions caused by HPV types 6, 11, 16, and 18 in females. The vaccine also has approval for the prevention of genital warts caused by types 6 and 11 in both males and females.

FDA: Gardasil approved to prevent anal cancer. U.S. Food and Drug Administration: News and Events. Dec 22, 2010, accessed Dec 28, 2010. Available at:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm237941.htm>

FROM THE MEDICAL LITERATURE ...

New prescription labeling requirements proposed ... The United States Pharmacopeial



Convention has proposed new requirements for the labeling of prescriptions. The primary intent is to make them more understandable to the patient. While laudable, we may need a bigger vial. For links to the proposal and for the opportunity to comment, see below.

USP seeks comments on proposed general chapter <17> prescription container labeling. Rockville, MD:

United States Pharmacopeial Convention. 2011 Jan 3. Available at:

<http://www.usp.org/USPNF/notices/generalChapter17.html>

Guidelines for MRSA ... first ones issued by the Infectious Diseases Society of America. Issues that are covered include: recommendations for the most common clinical syndromes encountered in adults and children, and vancomycin therapy (dosing, monitoring, alternate therapies).

Liu C, Bayer A, Cosgrove SE, Daum RS, Fridkin SK, Gorwitz RJ, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adult and children. Clin Infect Dis. 2011 Feb 1;52:1-38. Available ahead of print at:

<http://cid.oxfordjournals.org/content/early/2011/01/04/cid.ciq146.full.pdf+html>

▶▶▶ Some things are just worth passing along:

Cleaning for a Reason ... If you know any woman currently undergoing chemotherapy, there is a cleaning service that provides FREE housecleaning, once per month for 4 months while she is in treatment. All she has to do is sign up and have her physician fax a note confirming the treatment. Cleaning for a Reason will have a participating maid service in her zip code area arrange for the service. This organization serves the entire USA and currently has 547 partners. Pass this information along!



Cleaning for a Reason. Lewisville, TX. ©2011 [Accessed 2011 Jan 21]. Available at:

<http://www.cleaningforareason.org/>

Reviews of Note ...

- Brown EN, Lydic R, Schiff ND. General anesthesia, sleep, and coma. N Engl J Med. 2010 Dec 30;363(27):2638-2650.
- Connolly KR, Thase ME. If at first you don't succeed: A review of the evidence for antidepressant augmentation, combination and switching strategies. Drugs. 2011;71(1):43-64.
- Thacher TD, Clarke BL. Vitamin D insufficiency. Mayo Clin Proc. 2011 Jan;86(1):50-60.
- Burns CM, Wortmann RL. Gout therapeutics: new drugs for an old disease. Lancet. 2011 Jan 8;377:165-77.
- Neu J, Walker WA. Necrotizing enterocolitis. N Engl J Med. 2011 Jan 20;364(3):255-264.
- Rosen CJ. Vitamin D insufficiency. N Engl J Med. 2011 Jan 20;364(3):248-254.
- Meyer-Massetti C, Cheng CM, Schwappach DLB, Paulsen L, Ide B, meier CR, Guglielmo BJ. Systematic review of medication safety assessment methods. Am J Health-Syst Pharm. 2011 Feb 1;68:227-240.
- Morgado MP, Morgado SR, Mendes LC, Pereira LJ, Castelo-Branco M. Pharmacist interventions to enhance blood pressure control and adherence to antihypertensive therapy: Review and meta-analysis. Am J Health-Syst Pharm. 2011 Feb 1;68:241-253.

NEW RESOURCES in the DIC ...

- Zgarrick DP. Getting Started as a Pharmacy Faculty Member. Washington, DC: American Pharmacists Association, 2010.
- Janicak PG, Marder SR, Pavuluri MN. Principles and Practice of Psychopharmacotherapy. 5th ed. Baltimore: Wolters Kluwer Health/Lippincott, Williams & Wilkins, 2011.
- Drug Facts and Comparisons 2011. St. Louis: Wolters Kluwer Health/Facts and Comparisons, 2010.
- Billups NF, Billups SM, eds. American Drug Index 2011. St. Louis: Wolters Kluwer Health/Facts and Comparisons, 2010.
- Tatro DS, ed. Drug Interaction Facts 2011. St. Louis: Wolters Kluwer Health/Facts and Comparisons, 2010.
- DerMarderosian A, Beutler JA, eds. The Review of Natural Products. 6th ed. St. Louis: Wolters Kluwer Health/Facts and Comparisons, 2010.
- Grabenstein JD. ImmunoFacts; Vaccines and Immunologic Drugs 2011. St. Louis: Wolters Kluwer Health/Facts and Comparisons, 2010.
- Lemke TL. Review of Organic Functional Groups: Introduction to Medicinal Organic Chemistry. 5th ed. Baltimore: Wolters Kluwer/Lippincott Williams and Wilkins, 2012.
- Carvajal MJ, Armayor GM, Hardigan PC. Socioeconomic Profile of Pharmacists in South Florida: Who They Are, What They Do, How Much They Like It. Nova Southeastern University College of Pharmacy Monograph Series. Vol 1. Nova Southeastern University 2010.



The last "dose" ...

"There are no secrets to success. It is the result of preparation, hard work, and learning from failure."

--Colin Powell [1937 -]



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

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