Revised ACIP Recommendations for 2010-2011 Influenza Season:
The Advisory Committee on Immunization Practices (ACIP) has voted to expand the recommendation for the 2010-2011 annual influenza vaccination period to include all people 6 months of age and older. Next season's vaccine will be trivalent (with 3 different vaccine viruses) and will include an A/California/7/2009 (H1N1)-like virus, an A/Panama/45/2009 (H3N2)-like virus, and a B/Bengal/60/2008-like virus. The H1N1 virus recommended for inclusion in the 2010-2011 seasonal influenza vaccine is the same pandemic 2009 H1N1 virus used in the 2009 H1N1 monovalent vaccine. The universal vaccination recommendation is intended to protect people in higher-risk groups who are unaware of their risk factor as well as to stress the importance of influenza vaccination. It also points out the importance of protecting people 19 to 49 years of age who were hard hit by the 2009 H1N1 pandemic virus, as well as the likelihood of continued circulation next season and beyond.

Kapidex Name Change:
The name of Takeda's Kapidex™ (dexlansoprazole) has been changed to Nexium™ (dexlansoprazole) to avoid name confusion with the drugs Casodex (bicalutamide) and Kadian (morphine sulfate). Both agents are indicated for very different uses than dexlansoprazole (Kapidex™), which is approved for Gastroesophageal Reflux Disease (GERD) and Erosive Esophagitis. No other changes are planned for dexlansoprazole (Kapidex™) beyond the name change.

Sources:
www.ashp.org
www.cdc.gov
www.fda.gov
http://ginasthma.org
www.medscape.com
www.PTCommunity.com
www.pubmed.gov

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New clopidogrel (Plavix®) Boxed Warning:
FDA has added a Boxed Warning to the label for clopidogrel (Plavix®). The Boxed Warning is about patients who are poor metabolizers and therefore may not receive the full benefits of the drug. The Boxed Warning in the drug label will include information to:

- Warn about reduced effectiveness in patients who are poor metabolizers of clopidogrel (Plavix®). Poor metabolizers do not effectively convert clopidogrel (Plavix®) to its active form in the body because of low CYP 2C19 activity.
- Inform healthcare professionals that tests are available to identify genetic differences in CYP2C19 function.
- Advise healthcare professionals to consider use of other anti-platelet medications or alternative dosing strategies for clopidogrel (Plavix®) in patients identified as poor metabolizers.

It is estimated that 2% to 14% of the population are poor metabolizers; the rate varies based on racial background. FDA recommends that healthcare professionals should:

- Be aware that some patients may be poor metabolizers of clopidogrel (Plavix®). The effectiveness of clopidogrel (Plavix®) as a preventive therapy is reduced in these patients.
- Be aware that tests are available to determine patients' CYP2C19 status.
- Consider use of other anti-platelet medications or alternative dosing strategies for clopidogrel (Plavix®) in patients who have been identified as poor metabolizers.
- Be aware that although a higher dose regimen (600 mg loading dose followed by 150 mg once daily) in poor metabolizers increases antiplatelet response, an appropriate dose regimen for poor metabolizers has not been established in a clinical outcomes trial.
- Review the newly approved clopidogrel (Plavix®) drug label for complete information on the use of clopidogrel (Plavix®).

Drug Information Highlights:

- FDA has announced an ongoing safety review of oral bisphosphonates and risk of atypical subtrochanteric femur fractures. At this point, the data that FDA has reviewed have not shown a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures. FDA is working closely with outside experts, including members of the recently convened American Society of Bone and Mineral Research (ASBMR) Subtrochanteric Femoral Fracture Task Force, to gather additional information that may provide more insight into this issue. In 2008, FDA had requested information from all bisphosphonate drug manufacturers regarding this potential safety signal. Case reports had suggested that "atypical" subtrochanteric femur fractures were occurring at higher-than-expected rates in women taking bisphosphonates for osteoporosis. The agency noted that some research has already indicated that these fractures may simply be an outcome of osteoporosis.

- FDA has notified healthcare professionals and patients that, based on review of data from a large clinical trial and other sources, there is an increased risk of muscle injury in patients taking the highest approved dose of simvastatin (Zocor® 80 mg) compared to patients taking lower doses of simvastatin (Zocor®) and possibly other drugs in the "statin" class. FDA is also reviewing data from other clinical trials, observational studies, adverse event reports, and data on prescription use of simvastatin (Zocor®) to better understand the relationship between high-dose simvastatin (Zocor®) use and muscle injury.
<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Description</th>
<th>Applicant</th>
<th>FDA Status</th>
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</thead>
<tbody>
<tr>
<td>sitagliptin</td>
<td>Januvia®</td>
<td>Januvia® and Janumet® are now approved for coadministration with an insulin secretagogue (e.g., sulfonylurea) or insulin. Patients on Januvia® or Janumet® may require lower doses of the insulin secretagogue or insulin to reduce the risk of hypoglycemia.</td>
<td>Merck</td>
<td>FDA Approval New Indication 02/26/2010</td>
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<tr>
<td>sitagliptin/metformin</td>
<td>Janumet®</td>
<td></td>
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<tr>
<td>articaine HCl and epinephrine injection</td>
<td>TBD</td>
<td>Articaine HCl and epinephrine injection is an amide local anesthetic containing a vasoconstrictor indicated for local, infiltrative, or conductive anesthesia in both simple and complex dental procedures. It is approved for patients four years and older. It is for dental injection by sub mucosal infiltration and/or nerve block. The trade name has not yet been established.</td>
<td>Pierrel</td>
<td>FDA NDA Approval 02/26/2010</td>
</tr>
<tr>
<td>velaiglucerase alfa for injection</td>
<td>Vpriv™</td>
<td>Vpriv™ is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) in pediatric and adult patients with type 1 Gaucher disease. Patients currently being treated with imiglucerase for Gaucher disease can be switched to Vpriv™. Those on stable dosing of imiglucerase should begin treatment with Vpriv™ at that same dose. Vpriv™ is administered every other week as a 60-minute intravenous infusion.</td>
<td>Shire</td>
<td>FDA NDA Approval 02/26/2010</td>
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<tr>
<td>hydromorphone HCl extended release (ER)</td>
<td>Exalgo™</td>
<td>Exalgo™ is an opioid agonist indicated in a once daily dosage form for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time. Exalgo™ is a schedule II controlled substance and NOT intended for use on an as needed basis.</td>
<td>Alza</td>
<td>FDA Approval New Formulation Priority Review 03/01/2010</td>
</tr>
<tr>
<td>onabotulinum toxin A injection</td>
<td>Botox®</td>
<td>Botox® injection, an acetylcholine release inhibitor and a neuromuscular blocking agent, is now indicated for the treatment of upper limb spasticity in adults. Safety and efficacy of Botox® in the management of upper limb spasticity in pediatric patients and lower limb spasticity in adult and pediatric patients have not been established.</td>
<td>Allergan</td>
<td>FDA Approval New Indication 03/09/2010</td>
</tr>
<tr>
<td>triptorelin pamoate injectable suspension</td>
<td>Trelstar®</td>
<td>Trelstar®, a gonadotropin releasing hormone (GnRH) agonist, is now indicated for the palliative treatment of advanced prostate cancer at a dose of 22.5 mg every 24 weeks. Previously, lower strengths were administered every 4 or 12 weeks.</td>
<td>Watson</td>
<td>FDA Approval New Indication – Strength 03/10/2010</td>
</tr>
<tr>
<td>decitabine injection</td>
<td>Dacogen®</td>
<td>Dacogen®, a nucleoside metabolic inhibitor, is now indicated in an alternate dosage regimen for the treatment of patients with myelodysplastic syndrome (MDS). The new dosing regimen is a one hour infusion administered daily for 5 days and repeated every 4 weeks. A minimum of 4 treatment cycles with Dacogen® is recommended for MDS.</td>
<td>Eisai</td>
<td>FDA Approval New Dosage Regimen 03/11/2010</td>
</tr>
<tr>
<td>doxepin hydrochloride</td>
<td>Silenor™</td>
<td>Silenor® tablets are indicated for the treatment of insomnia characterized by difficulties with sleep maintenance. Doxepin is contraindicated if the patient is taking or has taken a monoamine oxidase inhibitor (MAOI) within the last two weeks. Doxepin is also contraindicated in patients with untreated narrow angle glaucoma or severe urinary retention. Doxepin has previously been available as 10, 25, 50, 75, 100 and 150 mg tablets and oral solution for the treatment of major depression.</td>
<td>Somaxon</td>
<td>FDA NDA Approval 03/17/2010</td>
</tr>
<tr>
<td>adapalene 0.1% lotion</td>
<td>Differin®</td>
<td>Differin® lotion, a retinoid product, is indicated for the topical treatment of acne vulgaris in patients’ ages 12 years and older. Differin has previously been available as a 0.1% cream and 0.1% and 0.3% gel.</td>
<td>Galderma</td>
<td>FDA Approval New Dosage Form 03/17/2010</td>
</tr>
<tr>
<td>carglumic acid</td>
<td>Carbglu®</td>
<td>Carbglu® is a Carbamoyl Phosphate Synthetase 1 (CPS 1) activator indicated as adjunctive therapy for the treatment of acute hyperammonemia due to deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS). Additionally, Carbglu® is indicated as maintenance therapy for the treatment of chronic hyperammonemia due to the deficiency of NAGS.</td>
<td>R &amp; R Registrations</td>
<td>FDA NDA Approval 03/18/2010</td>
</tr>
<tr>
<td>pramipexole extended release</td>
<td>Mirapex ER®</td>
<td>MIRAPEX ER is now approved in a once-daily, extended-release formulation to treat the signs and symptoms of idiopathic Parkinson’s disease (PD), which includes early and advanced PD. This latest indication adds the approval for advanced PD.</td>
<td>Boehringer Ingelheim</td>
<td>FDA Approved New Indication 03/19/2010</td>
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