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PHARMACY MONTHLY NEWSLETTER

SEPTEMBER 2, 2009

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In The News:

Metformin may significantly reduce the risk of developing pancreatic cancer in Type 2 DM according to an epidemiologic study that compared patients with pancreatic cancer to cancer-free patients based on use of insulin, secretagogues, metformin and sulfonylureas.

- ✦ Patients who had been on therapy with metformin alone or in combination with other agents had a 62% lower incidence of pancreatic cancer which was still significant after correction for other risk variables. [[Link](#)]
- ✦ Further studies are needed for validation but adds to the current known benefits of metformin in Type 2 DM as a first line agent.

FDA approved a new indication for **Xyzal® (levocetirizine dihydrochloride)** in the treatment of perennial allergic rhinitis or chronic idiopathic urticaria (hives) in patients **≥ 6 months** of age and seasonal allergic rhinitis in patients **≥ 2 years**. [[Link](#)]

FDA approved **Saphris® (asenapine)** an atypical antipsychotic for the short-term treatment of acute episodes of schizophrenia and bipolar I disorder in adults. It will be available as a dissolving tablet dosed twice daily. [[Link](#)][[Link](#)]

- ✦ Saphris will carry a black box warning like all atypical antipsychotics warning about the increased risk of death associated with off-label use to treat dementia-related psychosis. Saphris is not indicated for treatment in this population.

Bisphosphonates improve aortic stenosis? A retrospective study published in the American Journal of Cardiology found that there may be a decreased progression of aortic stenosis in osteoporosis patients treated with bisphosphonates. [[Am J Cardiol](#)] [[Am J Cardiol 2](#)]

- ✦ Progression of aortic stenosis in the patients receiving osteoporosis therapy (OT) was less than that of patients not receiving OT based on review of annual echo reports over a mean period of 2 and 1/2 years.
- ✦ While the mechanism is unclear, bisphosphonates are thought to store themselves in regions of the aortic valve and bind to the form of calcium deposited here. They may also secondarily impact numerous factors involved in calcium deposition in these tissues.
- ✦ Many limitations to the study, but supports the need for further studies to determine benefit for use in aortic stenosis.

Collaborative medication reviews in Heart Failure patients decrease hospitalizations according to a study out of Australia published in *Circulation: Heart Failure* this month. Patients who had their medication regimens reviewed by a physician and pharmacist had lower hospitalization rates (5.5%) than those who did not undergo a collaborative review (12%) within the 1 year follow up period. [[Link](#)]

Pharmacy—Clinical Sound Bytes:

- ✦ FDA approved a new indication for **Forteo® (teriparatide)** for the treatment of glucocorticoid-induced osteoporosis. [[Link](#)]
- ✦ FDA approved **Extavia® (interferon beta-1b)**, containing the same active ingredient as Betaseron® for the treatment of relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations. [[Link](#)]
- ✦ FDA approved **Sabril® (vigabatrin)**, an inhibitor of GABA metabolism, to treat infantile spasms in children 1 month - 2 years and for the treatment of refractory complex seizures in adults. Due to the risk of **permanent vision damage**, it will only be available through a restricted distribution program [[Link](#)]
- ✦ FDA approved **Embeda® (morphine extended-release)** as an alternative morphine product designed to deter abuse. [[Link](#)]

Safety Updates:

[Submit ADR^s to MedWatch Online!](#)

The FDA issued early communication regarding the safety of **Xenical®** and **Alli® (Orlistat)** following reports of possible liver injury. Association has not been proven and patients can continue taking these products at this time. [[Link](#)]

[Xenical/Alli®
GDH-PQQ Strips
CellCept®
Leukotriene inhibitors](#)

Test Strips containing glucose dehydrogenase pyrroloquinoline quinone (GDH-PQQ)

- The FDA re-issued a warning that test strips containing GDH-PQQ may falsely elevate glucose readings in patients receiving certain **dialysis solutions**, **immune globulin**, and **biologics**.
- This is unlikely to affect the majority of primary care patients. [[Press](#)], [[Patient Q&A](#)]

[Ask RPh to submit
ADR to Medwatch](#)



Roche reported cases of Pure Red Cell Aplasia in patients receiving **CellCept® (mycophenolate mofetil)**. [[Link](#)]

FDA issued updates to prescribing data regarding incidence of neuropsychotic events associated with the **leukotriene inhibitors** [**Singulair (montelukast)**, **Accolate (zariflukast)** and **Zyflow (zileuton)**]. Updates to prescribing data are available here. [[Link](#)]

- Link to ALL June 2009 [labeling changes](#) (i.e., post-marketing ADR updates) [[Link](#)]

* **Example: Amaryl® (glimepiride)** updated drug information to include 'Drugs that may potentiate the hypoglycemic action of sulfonylureas: disopyramide, fluoxetine, and quinolones' in drug interactions section.

New Generic Approvals*:

[Each have a Medicare exception from Tier changes until 1/1/2010]

Valacyclovir, generic for Valtrex®; **alendronate** generic for Fosamax®; **sumatriptan**, generic for Imi-trex®; **zaleplon**, generic for Sonata®; **galantamine**, generic for Razadyne/Razadyne ER®.

Other recent new generics include: Zerit, Depakote, Depakote ER, CellCept, Prograf





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Emerging Therapies & the Drug Pipeline:

{ [Apixaban](#) }

Acute Treatment of Migraine—Zelrix® (sumatriptan transdermal) is being investigated as a new dosage form of sumatriptan.

- Zelrix would be the first transdermal dosage form of the “triptan” class of medications with the advantage of overcoming migraine treatment barriers including nausea, side effects due to peak plasma concentrations, and inconsistent drug absorption.
- Phase III Trials report treatment success with patients reporting relief within 2 hours of application with minimal side effects.

Thromboprophylaxis—Apixaban is an oral factor Xa selective inhibitor being investigated as an anticoagulant.

{ [Zelrix®](#) }

- In a study published in NEJM this month, Apixaban was compared to enoxaparin for prevention of thrombosis after knee replacement surgery. Apixaban could not be considered non-inferior to enoxaparin in the study.
- Apixaban was associated with lower rates of clinically relevant bleeding with a similar adverse effect profile to enoxaparin.
- Apixaban would be the first ORAL Xa inhibitor if approved. Current Xa inhibitors are only available as injections.

Pharm.D. Monthly Q&A Review:

Incoming e-mail Question: If I only take my Zetia (ezetimibe) with a fatty meal, about every 10 days, am I still benefiting from it?

Excerpt of Outgoing e-mail Answer:

- **NO.** Ezetimibe selectively inhibits absorption of both dietary and biliary cholesterol in the brush border of the small intestine so this would appear to make sense initially. The result is decreased hepatic cholesterol and increased LDL receptor activity which helps clear LDL from the bloodstream. However, most cholesterol in the intestine comes from bile not diet and LDL can be lowered in patients with no cholesterol intake. Therefore, the patient likely receiving little benefit from taking this way. However, intake of lower daily doses (5mg vs 2mg) have shown similar efficacy in lowering LDL (16% vs 12%) superior to doubling statin dose (6%).

Disease State Or Literature Update:

Literature Update: Cardiovascular Risk Associated with Thiazolidinediones

A study published in the British Medical Journal this month reported results of a retrospective study (n = 39,736) that indicate **Avandia® (rosiglitazone)** posed a clinically significant greater risk of heart failure and death, but not MI, as compared to **Actos® (pioglitazone)**.

Results and conclusions from previous trials:

- **DREAM (Diabetes Care 2006)** - Primary goal was to assess the effects of ramipril & rosiglitazone on the progression of Type 2 DM. An increase in cardiovascular (CV) events was noted as a secondary outcome, especially in heart failure (HF) patients.
- **ADOPT (NEJM 2006)** - Primary outcome was the efficacy of rosiglitazone, metformin, and glyburide in maintaining glycemic control. An increase in CV events was noted as a secondary outcome in both metformin & rosiglitazone at about the same rate. Events in CHF patients were greater in the rosiglitazone group than both the metformin and glyburide groups.
- **RECORD (Lancet 2009)** - Directly studied the CV risk of rosiglitazone against metformin + sulfonylurea therapy (active control). Results showed an increase risk in HF which was statistically significant and in MI which was not statistically significant.

What the recent study adds:

- Supporting evidence that rosiglitazone is associated with negative CV outcomes, especially in HF patients.
- Comparison of the risk of these events to the comparator agent, pioglitazone.

Clinical Significance: While data is still inconclusive regarding the safety of these medications long term, there is no benefit in using one agent over the other for glucose control. There is now data to suggest that pioglitazone is the safer of the two treatment options.

Formulary Updates:

IHA Starts New Value Initiative

[Link to IHA Formulary](#)

IHA has begun an initiative they are referring to as “**Value Prescribing**” which aims to help control the rising costs of prescription drugs by finding the best combination of quality (efficacy) & cost for various therapies. The program will focus on statin therapy because despite many cost reduction programs they still represent the best opportunity to achieve ‘value prescribing’ and help reduce costs.

Patients WANT guidance from their physicians Providers do NOT appear to be asking

“Most wanted providers to ask about medication affordability (81%), consider cost (86%), offer choices (70%), and to persuade them or decide for them which medication to use (88%)” — “Few said providers asked about affordability (17%), usually or always discussed prices (19%), or offered choices (45%) — [[Journal of the American Geriatrics Society 2007, 1974,1977.](#)]

| | Drug | Average Annual Co-pay | Average Retail Cost of Drug | Average Annual Retail Cost of Drug |
|--------|-------------|-----------------------|-----------------------------|------------------------------------|
| Tier 1 | Lovastatin | \$48 | \$156 | \$108 |
| | Pravastatin | | | |
| | Simvastatin | | | |
| Tier 2 | Crestor® | \$300 | \$1,596 | \$1,296 |
| Tier 3 | Lipitor® | \$420 | \$1,860 | \$1,440 |
| | Vytorin® | | | |

*All meds tier 1 unless otherwise specified; §ADR = Adverse Drug Reaction; PAR = Prior Auth Req'd; † NDA = New Drug Application