



Second Quarter 2010  
Vol. VII, Issue 2

## Special Points of Interest:

- P&T Update
- Policy and Procedures Update
- New FDA Approvals
- 2nd Quarter 2010 Employee of the Quarter

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## P&T Update

### Formulary Addition/Deletion

- Hyaluronidase human injection (Hylenex Recombinant) Hylenex® a recombinant Hyaluronidase is an adjuvant to increase the absorption and dispersion of other injected drugs, for subcutaneous fluid administration, for improving absorption of radio-opaque agents. – Formulary addition not deemed necessary at this time
- Molindone and Ethiodized Oil 37% - Manufacturer discontinued – Motion to delete from formulary – Approved
- Penicillin G Na, Nelfinavir and Saquinavir formulary deletion – Approved
- Thrombin Bovine – Motion to delete of Thrombin Bovine JMI product. Pharmacy will only stock Recothrom® – Approved
- Budesonide/formoterol fumarate dehydrate (Symbicort®) - addition Budesonide is a combination inhaler containing a synthetic corticosteroid and a long acting bronchodilator that exerts agonistic effects on beta (2)-adrenergic receptors. It is FDA approved for asthma and COPD maintenance therapy. – Formulary addition of budesonide/formoterol (Symbicort®) – Approved
- Similar drugs currently on formulary include fluticasone (Flovent®), salmeterol (Serevent®), and triamcinolone (Azmacort®). – Formulary deletion of triamcinolone acetonide (Azmacort®) – Approved
- Motion made to automatically substitute orders for fluticasone propionate/ salmeterol (Advair®) to budesonide/formoterol fumaratedehydrate (Symbicort®) – Automatic substitution approved
- Pentazocin (Talwin®) injection one purchase within the past three years, formulary deletion – Approved
- Urokinase (Abbottkinase®) is not available commercially, formulary deletion – Approved
- Sodium Chloride 5% IV solution no longer available commercially, formulary deletion – Approved
- Levalbuterol (Xopenex®) automatic therapeutic exchange with albuterol for adults only – Approved
- Fluticasone/salmeterol (Advair®) automatic therapeutic exchange with Budesonide/formoterol (Symbicort®) – Approved

### Policy and Procedures Update

- ADR/ME policy updated as follows: Revised HARM scoring
  - Mild ADR/ME (A, B1, B2) – Near miss event, no harm,
  - Moderate ADR/ME (C, D, E) – No harm/Moderate harm,
  - Severe/significant ADR/ME event (F, G, H, I) – High Harm/Death.
- All potential IV drug incompatibilities, must be reported by RN (if observed prior to/during administration) or RPH as prevented ME on the patient safety net. – Approved

### IV to Oral interchange policy update

- Revisions include interchange after 48 hours, addition of new medications to the list (azithromycin, ciprofloxacin, clindamycin, digoxin, doxycycline, famotidine, folic acid, levetiracetam, multivitamin, thiamine, trimethoprim/Sulfamethoxazole and voriconazole) and automatic iv to oral substitution by the pharmacist for medications that are not antimicrobials. – Approved

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## IV to Oral interchange policy update

(Continued from page 1)

- Restriction of intravitreal/intraocular/topical eye drops for amphotericin B, cidofovir, foscarnet Voriconazole will require Ophthalmology approval Addition of polymyxin B to the restricted antibiotic list, default duration of approval for any restricted antibiotic will be 7 days unless specified otherwise by the physician – Approved.

New FDA approved indications for formulary medications – The P&T Committee will evaluate new indications for formulary medications on a monthly basis. – Approved

- Motion made to approve new indications for formulary medications: Aripiprazole: irritability associated with autistic disorder in pediatric patients Colchicine: prophylaxis of gout flares Influenza virus vaccine (Fluarix®): prevention of influenza A/B virus in pediatric patients Ziprasidone: maintenance treatment of bipolar 1 disorder
- The guidelines for antibiotic lock solutions were presented – Approved

## Miscellaneous/IV medication guideline changes

1. Aminocaprioc acid IVPB allowed in out- patient (OP) area
2. Daptomycin (non-formulary) added into guideline for all areas
3. Dexmedetomidate continuous infusion (CI) added for ICU only
4. Ethacrynate IVPB allowed in addition to IV push
5. Folic acid IVPB over 30 min. allowed in addition to IV push
6. Hepatitis B immune globulin IVPB allowed to all areas (transplant)
7. Iron dextrans & sucrose large doses IVPB allowed to all areas
8. Methylprednisolone IVPB allowed in doses >125 mg (change from 500mg limit) for all areas
9. Peramivir (non-formulary) added to the guideline for ICU only
10. Tigecycline (non-formulary) added to the guideline for all areas
11. THAM added into the guideline for ICU only Vancomycin IVPB allowed in out-patient area

## Bad Bugs, Few Drugs: The Growing Problem of Antimicrobial Resistance

Antibiotic resistance among gram-positive and gram-negative bacteria is a growing problem in today's clinical setting. Numerous studies have demonstrated that infections due to resistant organisms are associated with significant increases in hospital length of stay, mortality, and healthcare costs.<sup>1,2</sup> These resistant organisms are commonly referred to as the ESKAPE pathogens and include *Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter* species. Many of these resistant organisms are not susceptible to several classes of antibiotics currently used in clinical practice, and the development of new antibacterial agents is waning.<sup>3</sup> Therefore, practitioners often have limited treatment options to manage patients with resistant infections.

Several professional organizations have acknowledged the increasing problem with antimicrobial resistance, including the Infectious Diseases Society of America (IDSA). In early 2010, IDSA launched the 10 x '20 initiative, which supports the development of 10 novel antimicrobial drugs by 2020.<sup>4</sup> There has also been recent focus on the development of institutional antimicrobial stewardship programs to optimize clinical outcomes with antimicrobial therapy while minimizing adverse events and the emergence of resistance. IDSA guidelines for the establishment and implementation of antimicrobial stewardship programs have been published.<sup>5</sup> Appropriate use of antimicrobials requires a multidisciplinary effort from physicians, nurses, pharmacists, infection control practitioners, and other healthcare professionals.

There are several strategies that can be implemented to optimize antimicrobial usage at The University Hospital. Strict adherence to infection control practices is essential to prevent the spread of resistant pathogens. Orders for antimicrobial therapy should be reviewed on a daily basis for appropriateness of indication, dose, duration, and other factors. Timely streamlining or de-escalation of empiric antimicrobial therapy should be done based on microbiological findings. The management of patients at The University Hospital is greatly affected by the presence of drug-resistant pathogens. Healthcare practitioners must ensure optimal antimicrobial use to provide the best patient care and avoid unintended consequences.

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## **SPRIX® - First Non-Narcotic Intranasal Analgesic for Moderate to Moderately Severe Pain Approved by FDA**

Known as the “silent epidemic” in the U.S., pain has been affecting the lives of millions of Americans for decades. According to the National Centers for Health Statistics, over 76.2 million Americans suffer from pain, which is more than the number of Americans suffering from diabetes, heart disease and cancer combined. This plays a big role in health care costs in the U.S. as well as personal financial burdens. Nonetheless, the unfortunate physical and emotional toll that patients face when in pain has led to an enormous increase in the use and misuse of pain medications.

The two main classifications of pain are acute and chronic pain. Acute pain mostly results from disease, inflammation, or injury to the tissues. Depending on the type and severity of acute pain, some of the common treatments are pain relievers such as acetaminophen, NSAIDs, opioids, anti-depressants, and anti-seizure medications. While agents such as oral NSAIDs are used for mild to moderate pain, opioids and parenteral ketorolac tromethamine are utilized by several institutions for moderately severe to severe pain. However, since ketorolac is an IV/IM formulation, the side effects and inconvenience for patients especially post operatively, has caused it to fall out of favor.

This past May 2010, the FDA approved Roxro Pharma’s intranasal formulation of ketorolac tromethamine called SPRIX® which is indicated for short term (up to 5 days) management of moderate to moderately severe pain. This new formulation achieves peak blood levels as quickly as the IM injection and can conveniently provide pain relief outside of the hospital setting. According to the article Pharmacokinetics and Safety of Ketorolac Following Single Intranasal and Intramuscular Administration in Healthy Volunteers, intranasal ketorolac has been shown to be used as a therapeutic alternative to IM administration and may even provide additional advantages in a clinical setting.

Additionally, looking at an article on the safety and efficacy of intranasal ketorolac, the rates of pyrexia and tachycardia were

shown to be significantly lower in the ketorolac group compared to the placebo group. The study results also showed that the supplemental morphine use during the first 24 hours was significantly less in patients receiving ketorolac than in the placebo group.

The major advantages to note here are that SPRIX® “fills the need for a new non-opioid, non-injectable option for ambulatory pain control, while it minimizes the potential for abuse as well as the negative side effects associated with narcotic pain relievers.” Furthermore, it provides the same moderate to moderately severe pain relief as its narcotic alternatives. Though it is too early to say, this new expansion in the area of pain medications and research may lead to new and improved drugs formulations and ultimately increase the quality of life of Americans.

Contributed by:

Priya Amin, Pharm.D. Candidate 2012

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## **New Class of Drugs for the Treatment of Type 2 Diabetes Mellitus**

Diabetes is a long term disease marked by high levels of glucose in the blood. Type 1 Diabetes is characterized as an autoimmune disease of the pancreas, usually resulting in a lack on insulin. Therefore, the treatment of choice for Type 1 Diabetes is none other than insulin therapy. Type 2 Diabetes, on the other hand, can be due to insulin resistance or relative insulin deficiency. Therefore, treatment for Type 2 Diabetes includes a wide range of options including diet modification, exercise, and a spectrum of pharmacological agents.

Until recently, pharmacological management of Type 2 diabetes could be classified under the following drug classes: sulfonylureas, meglitinides, biguanides, thiazolidinediones, alpha glucosidase inhibitors, DPP-4 inhibitors, and incretin mimetics. These medications mainly work by either increasing insulin sensitivity, increasing secretion of insulin, or decreasing the hepatic absorption of sugar. However, a new class of drugs may change the guidelines for therapy in the near future.

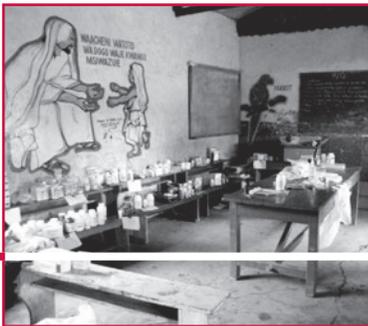
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## Volunteers in Medical Missions – Merlin in Tanzania

The alarm went off exactly at 6:30 AM. Still tired from a 24 hour flight, my body didn't seem to want to move. As I opened my eyes and looked across the room through the white mosquito net draped around me, I realized that I was halfway across the world from home. After five months of planning, I was in Africa on a medical mission trip that I had hoped to participate in for a long time. Our team, consisting of five doctors, five nurses, one counselor, and one pharmacist, started getting ready for our first day in the beautiful country of Tanzania.

The trip began with more excitement than I had anticipated. As we were flying over the Atlantic Ocean on the flight from Atlanta to Amsterdam, an elderly passenger fainted in the aisle close to where we were sitting. Most passengers were asleep when a flight attendant requested the presence of any doctors on the flight. Sitting behind me, Dr. Nancy Alexis, one of the senior doctors on our team, responded to the announcement and was by the unconscious passenger in a matter of seconds. She was able to revive the gentleman within a few minutes. From that moment on, I was confident that this trip would be nothing less than extraordinary.



We arrived at Kilimanjaro Airport in Tanzania around 10 pm on May 3rd. For the duration of our stay in Tanzania, we were housed at a guesthouse run by the Usa River Rehabilitation Center (URRC). URRC is a place for people with and without disabilities

to live, learn, and work together. On a tour, we observed that the URRC offers the young disabled the opportunity to learn the following vocations - Carpenter, Tailor, Shoemaker, Welder. URRC went even a step further through their orthopedic workshop, where many prostheses and orthoses are made, allowing those disabled to live as independently as possible. Throughout our stay, we observed URRC touch the lives of many, including my team members and I.

Our day usually started with a quick breakfast at 7 AM, followed by chapel service at 7:30 AM with a lively student choir that left us energized for the day. From the first day, I was left with the most heartfelt memories of this chapel. Everyday, a disabled man would leave his wheelchair outside and walk on his hands into the chapel, with his three year old child walking closely behind him. He would drag himself up onto a bench and pull his child up onto his lap. Each day, I left the chapel encouraged by his strength and willful spirit to begin a day of service.

Two areas that our medical mission trip focused on were Kilala and Valesca. Kilala, comprised of a town population, was

15 minutes away from the URRC guesthouse. Valesca, a remote village with a high pediatric population, could only be reached by a 30 minute

drive on a small dirt road connected to the main road. In both areas, admissions, triage, and doctors were set up in the local church, and the pharmacy was set up in a nearby kindergarden classroom or building. Our days usually started at 9 and ended at 5 with a quick lunch break around 12:30. Each station had an interpreter, without whom none of this would have been possible. Long lines of patients were formed before we even reached our stations, and it remained that way throughout the day. No matter how many patients were waiting, the team made sure that no patient was left unseen.



From a pharmacy perspective, this experience was truly rewarding. As a pharmacist, I appreciated having the privilege of changing incorrect orders to appropriate medications while ensuring the effectiveness of the therapy and not comprising the safety of the patients. This was especially true in Valesca, where there was a high number of children and pregnant woman. Thus, compounding also became a major part of my role as we didn't have the luxury of ordering certain formulations. In addition, although having an interpreter was extremely helpful, in certain situations I had to resort to my own version of sign language in order to convey the message to the interpreter and the patient. Overall, this experience has become one of the most worthwhile experiences I have had as a pharmacist.

During my return flight to the United States, I could not help but to wonder when I would be able to go on another medical mission trip. For those who are interested in going on such a trip, please keep in mind that this cannot be an overnight



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## Volunteers in Medical Missions

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decision. A trip of this nature, especially if it is international, will cost a lot of money. Thus, planning ahead in terms of finances is crucial. Of course, there are multiple ways to fundraise, but some organizations require you to deposit a portion of the cost months in advance because they need to book flights. Thus, one has to be prepared to pay the full cost of the trip and any additional expenses they wish to spend for the people they will be caring for on the mission trip. Also, there are many organizations that bring volunteers together for such trips.

Thus, researching different organizations becomes an important part of this process. I sent my application to Volunteers in Medical Mission (VIMM) because not only have they been involved in bringing healthcare professionals together for such trips since the 1980s, but they also take care of all details such as flight plans, housing, meals, and travel. VIMM also purchases the medications and supplies, but they



allowed me to bring additional medications that I purchased since I was afraid that we wouldn't have enough to distribute to our patients. Last but not least, having a good support system is very important. I definitely found this in my family, friends, church, and the UMDNJ Pharmacy Department, to whom I am forever grateful.

## Microsphere Treatment Gains FDA Approval for Liver Cancer Treatment

Liver cancer is currently the fifth most common cancer in the world, killing almost all diagnosed patients within one year. According to the World Health Organization, liver cancer was responsible for 610,000 deaths worldwide in 2009<sup>1</sup>. 90-95% of liver cancers are "primary", arising from liver cells, and are known as hepatocellular cancer or carcinoma. Alternatively, metastatic or secondary liver cancer refers to a cancer that has spread to the liver, having originated in other organs such as the colon, stomach, pancreas, breast, and lung<sup>2</sup>. Primary liver cancers occur in livers damaged by birth defects, alcohol abuse, or chronic infection such as hepatitis B and C, hemochromatosis and cirrhosis. Certain herbicides, chemicals such as vinyl chloride and arsenic, and smoking are thought to increase the risk. Current treatment options for liver cancer depend on the stage the cancer is in, and the overall patient condition. The only proven cure for a solitary, small (<3cm) tumor is liver transplantation. Other standard therapies including chemotherapy, partial hepatic resection surgery, chemoembolization, ablation, and proton beam therapy have failed to produce significant decreases in mortality until now<sup>2</sup>.

A new radiological treatment that utilizes intra-arterial yttrium-90 microspheres has been shown to extend life for more than three fourths of hepatocellular carcinoma patients who are not eligible for surgery<sup>3</sup>. This is especially important for many patients who also have cirrhosis in addition to liver cancer and cannot tolerate liver resection surgery.

The unique interventional radiological treatment combines the radioactive isotope Y-90 into microspheres that deliver

radiation directly to the tumor, without harming healthy cells. The microspheres are injected through a catheter from the groin into the liver artery supplying the tumor, where they release local radiation and result in cell death<sup>3</sup>. A single-center prospective study of 291 patients with hepatocellular carcinoma treated with intra-arterial Y-90 showed a 7.9 month time to progression. According to Study investigator Riad Salem, MD, MBA of Northwestern Memorial Hospital in Chicago, "among oncological standards for this disease, the findings were extremely promising"<sup>3</sup>. Although surgical removal of liver tumors is the only accepted "cure", it is not a viable therapy option for over three fourths of hepatocellular carcinoma cases. Currently, the US FDA has approved Y-90 for the treatment of unresectable hepatocellular carcinoma, opening the door to investigate alternative nonsurgical therapies for the treatment of liver and other serious cancers.

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## New Antiplatelet Drug for Acute Coronary Syndromes: Ticagrelor

Coronary heart disease and acute coronary syndromes are a major cause of morbidity and mortality in the United States. Antiplatelet drugs reduce the risk of heart attack, unstable angina, stroke, and cardiovascular death in patients with a history of cardiovascular disease. Plavix® (clopidogrel) is one of the top-selling medications in the world, but since its recent Black Box Warning indication in March 2010, patients and physicians may be looking for other alternatives. Effient® (prasugrel) is another antiplatelet prodrug, which is approved for reducing risk of recurrent MI and stent thrombosis. It does not have an FDA black box warning. Prasugrel claims to be a "stronger" antiplatelet drug, but causes increased risk of intracranial bleeding. Both medications are thienopyridine prodrugs that block the P2Y12 binding site on platelets to inhibit aggregation.

Ticagrelor is an oral, non-thienopyridine P2Y12 receptor antagonist that does not require enzymatic activation by CYP450 isoenzymes. It is the first of its new chemical class: cyclo-pentyl-triazolo-pyrimidines. Since no enzymatic activation is needed for drug activity, this new drug avoids variability to produce a more consistent antiplatelet effect. This gives the drug an advantage over clopidogrel, whose black box warning warns of its reduced effectiveness in CYP2C19 poor metabolizers. Ticagrelor is also reversible, eliminating the need to withhold antiplatelet medications like clopidogrel and prasugrel 5 to 7 days prior to CABG. A 24 to 72 hour hold is sufficient.

A 2006 study demonstrated that ticagrelor, in doses over 100mg twice daily, produces a faster and more effective inhibition of platelet aggregation than clopidogrel. The DISPERSE-2 study showed ticagrelor in NSTEMI patients produces a more rapid effect that lasts longer. The PLATO study for patients with or without STEMI showed ticagrelor significantly reduces the rate of death from vascular causes and MI. However, there is an increased rate of non-CABG-related major bleeds and intracranial bleeding. Adverse reactions from ticagrelor include self-limiting dyspnea and ventricular pauses.

Clinical studies of this new oral antiplatelet drug demonstrate the safety, efficacy, and superiority over clopidogrel. Ticagrelor reduces the risk of vascular death and MI, which have not been demonstrated by clopidogrel or prasugrel.

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## New Class of Drugs for the Treatment of Type 2 Diabetes

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In the human body, there are two sodium-glucose cotransporters (SGLTs), which serve to reabsorb glucose. SGLT1 works in the intestine and kidneys, while SGLT2 works specifically in the proximal tubules of the kidney.

Inhibiting SGLT2 is proposed to block the reabsorption of glucose in the kidneys, resulting in hyperglycosuria and even weight loss. Since these drugs do not target the pathological defects associated with T2DM, "they represent a potentially promising new option in the treatment of diabetes."<sup>2</sup>

Currently, several pharmaceutical companies have investigational drugs in phase II and phase III studies. "Some reported side effects include both constipation and diarrhea, nausea, and reports of hypoglycemia, and some women developed vaginal infections (presumably because of the high

glucose concentration in the urine allowing yeast organisms to flourish)."<sup>3</sup> J&J's Canagliflozin and BMS/AZ's Dapagliflozin are predicted to be launched as soon as 2013. Although this new class may not be able to compete with first line medications like metformin, it will be interesting to see what the future of therapy holds and what global impact this new class will have on the treatment of diabetes.

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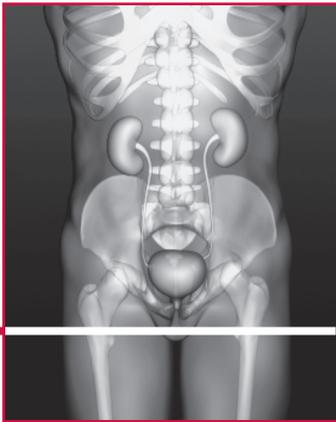
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## Everolimus - A New Treatment For Renal Cancer

In the last year alone, fifty-eight thousand people contracted kidney cancer and thirteen thousand died from it.<sup>1</sup> While surgery can act as a potential cure before metastasis, the prognosis grows far worse after it has spread. At this point, surgery is followed up by chemotherapy, radiology, or a combination of the two in order to attempt to stop the spread and kill the metastatic cells. In March of 2009 the FDA approved a new drug to treat renal cell carcinoma, the most common form of kidney cancer.<sup>2,4</sup>



Everolimus works by inhibiting mammalian target of rapamycin (mTOR), which is normally responsible for regulating cell growth, survival, proliferation, and motility, as well as protein transcription and other related functions.<sup>3</sup> By stopping mTOR, Everolimus can block cell division, a major obstacle to any rapidly dividing cells, especially cancer cells. This mechanism

also explains its 2010 indication for combating organ transplant rejection, since the immune cells involved in organ rejection are also rapidly dividing. Everolimus is also capable of inhibiting the effects of vascular epithelial growth factor (VEGF), allowing it to stop blood vessel growth to tumors and

thus stunt their growth.<sup>3</sup>

Everolimus was approved on the basis of a trial in metastatic renal cell carcinoma patients who were not successfully helped with sunitinib or sorafenib.<sup>2</sup> Moreover, while it did enhance progression-free survival, everolimus did not show an improvement in ultimate survival,<sup>4</sup> thus limiting its use to merely buying a little more time for patients not sufficiently helped by other drugs. There is not enough data to support its use as a first-line drug for renal cancer but it will likely stay in use due to the potential for some benefit.

Contributed by:  
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## Strativa Gets FDA Approval of Zuplenz Oral Soluble Film

Over the July 4th holiday weekend, Strativa Pharmaceuticals announced FDA approval of their drug, Zuplenz® (ondansetron) oral soluble film, for the "prevention of postoperative, highly and moderately emetogenic cancer chemotherapy-induced, and radiotherapy-induced nausea and vomiting."<sup>1</sup>

Distinct from Zofran ODT®, the orally dissolving tablet form of ondansetron by Glaxo Smith Kline (GSK), Zuplenz uses MonoSol Rx's PharmFilm® technology to deliver the drug without water by dissolving on the tongue. For patients suffering from nausea and vomiting, even small amounts of water needed to take medications can cause uneasiness and exacerbate symptoms.

Strativa, a division of Par Pharmaceutical Cos., presented clinical data showing the bioequivalence of 8 mg Zuplenz to GSK's 8 mg Zofran ODT when given orally with or without food and/or water, ultimately leading to the FDA's approval of the first prescription oral soluble film.

The approval of Zuplenz with PharmFilm® technology, available in retail pharmacies at the end of 2010, has shown the pharmaceutical industry another dosage form possibility for developing drugs and even drugs already on the market.

Contributed by  
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## Employee of the 2nd Quarter

### Harry Cuartas

The Pharmacy Department would like to introduce the second quarter Employee of the Quarter, Harry Cuartas. Congratulations Harry on a job well done.

Harry's coworkers think he is superb, cool and exemplary. Harry always offers to go on deliveries. He's fast and has a great

attitude. In addition to always finding solutions to unexpected problems, Harry helps maintain an efficient and fun work atmosphere. He is definitely an example for his co-workers to emulate.

Harry has been with UMDNJ since 2008 and we knew he was exceptional when we asked him during his interview, "What is one word your current boss would use to describe you?" and Harry responded, "Multifaceted." He was absolutely right.

Please join us in congratulating Harry for being the second quarter's classy essential piece!



## FDA to hold public meeting on Avandia® (rosiglitazone maleate)

On July 13-14, the Food and Drug Administration will hold a public Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, focusing on the cardiovascular safety of GlaxoSmithKline's Avandia® (rosiglitazone maleate) tablets. The antidiabetic drug already contains a black box warning for increased risk of congestive heart failure and myocardial ischemia. GSK also manufactures

two other drugs containing rosiglitazone, Avandamet® (rosiglitazone with metformin) and Avandaryl® (rosiglitazone with glimepiride).

Avandia®, approved in 1999, is part of a class of medications called thiazolidinediones that increase insulin sensitivity. It is indicated, with diet and exercise, for the treatment of

hyperglycemia in adult type 2 (non-insulin dependent) diabetes mellitus. Type 2 diabetes mellitus is a chronic disease marked by high levels of glucose due to insulin insensitivity or resistance. Complications of type 2 diabetes include

glaucoma, kidney disease, stroke, and heart attack. According to the National Institute of Health (NIH) almost 8% of the population, or 23.6 million people, have diabetes.

The public meeting will present data specific to rosiglitazone with results from the Rosiglitazone Evaluated for Cardiac Outcome and Regulation of Glycemia in Diabetes (RECORD) Trial, observational data, health claims data, and a meta-analysis of controlled clinical trials. The FDA will also present its meta-analysis of several trials of ACTOS (pioglitazone hydrochloride) tablets, another thiazolidinedione with the same indication as rosiglitazone. Based on the meeting, the FDA may potentially recommend the removal of Avandia® from the market.

Contributed by:  
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#### References:

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