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A STUDENT-OPERATED NEWSLETTER BY THE ST. JOHN'S UNIVERSITY COLLEGE OF PHARMACY AND HEALTH SCIENCES' RHO CHI BETA DELTA CHAPTER

Inside This Issue

An Interview with an FDA Preceptor: Pharmacist's Role at the FDA

By: Melissa Roy, Co-Copy Editor [Graphics focused]

Our dedicated preceptor Kimberly Defronzo, RPh, MS, MBA is currently a Consumer Safety Officer at the Food and Drug Administration (FDA). She attended the University of Connecticut School of Pharmacy for her Bachelors of Pharmacy. She then went to St. John's University College of Pharmacy and Health Sciences to obtain her Masters in Industrial Pharmacy and later received an MBA in Marketing from Rutgers University Graduate School of Management. She is currently a Consumer Safety Officer but has worked as a Reviewer for the FDA approving/rejecting proposed proprietary/trade/brand names of drug products. Prior to joining the FDA, she held various positions in retail, hospital, and pharmaceutical settings. Her journey as a pharmacist has been unique and unconventional.

As an APPE preceptor for St. John's PharmD students, she finds great joy in being able to provide students with the opportunity to learn about the FDA. She strives to provide an enjoyable and educational environment for her students while focusing on their professional and personal development. Through her dedication, students are given the opportunity to experience this unique rotation where they are able to witness the FDA at work. A rotation at the FDA will expose students to the possibility of yet another rewarding career path for pharmacists. Our interview with her provided us with an insight and appreciation of how interesting it is to be a pharmacist at the FDA.

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Combating Counterfeit Drugs

By: Azia Tariq, Staff Editor

With the sale of counterfeit drugs reaching an alarmingly higher rate than ever, The U.S Food and Drug Administration (FDA) in collaboration with the Skoll Global Threats Fund, the U.S. Pharmacopeia (USP), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the multi-agency President's Malaria Initiative (PMI), employed a new method for detecting these fake medications last April. The new tool, called CD-3, will serve to identify contaminated or substandard anti-malarial medications.[1] There are huge implications for this new technology, as it could play a pivotal role in FDA's fight against counterfeit drugs.

According to the WHO, worldwide sales of counterfeit medications reached $75 billion in 2010

A counterfeit drug is defined by the World Health Organization (WHO) as "…one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."[2] The sale of counterfeit medicine is a lucrative global industry. According to the WHO, worldwide sales of counterfeit medications reached $75 billion in 2010.[3] U.S. Attorney Barry Grissom reported that the FDA's Office of Criminal Investigation uncovered an internet pharmacy that had sold approximately $1.4 million worth of misbranded and counterfeit drugs, including controlled substances.[4] The site offered more than forty prescription drugs such as Zoloft® (eertraline HCl), Lipitor® (atorvastatin calcium), Cialis® (tadalafil), Viagra® (sildenafil citrate), and Xanax® (alprazolam).

Some of the most abundantly sold counterfeit drugs are under the guise of ED treatments

Counterfeit pharmaceutical products appear nearly identical to genuine medications so that it is often impossible to discern the authenticity of the product with the naked eye, even for a licensed professional. Because of this, patients can be at risk of exposure to medicines that may be contaminated or improperly stored and transported, even with vigilant inspection. Furthermore, the medications could be advertized as one drug, but actually be mislabeled or have a completely different active ingredient. The drugs could be expired, have a different strength than advertized, or not have any active ingredient. In Singapore, 150 people were admitted to the hospital for severe hypoglycaemia, four of which died and seven of which suffered severe brain damage.[3] They had reportedly taken counterfeit drugs promising to treat erectile dysfunction (ED), but instead contained a high dose of glyburide, a powerful anti-hyperglycemic for diabetes.

Some of the most abundantly sold counterfeit drugs are under the guise of ED treatments such as Viagra® (sildenafil citrate), Levitra® (vardenafil HCl), and Cialis® (tadalafil).[5] Consumers order these prescription drugs from websites they are not familiar with and unknowingly put themselves in danger. The motives can be explained easily enough. While an in-person consultation with a doctor may be embarrassing for the patient, buying the drug from an online pharmacy provides anonymity. Similarly, the social stigma often associated with having an STD may drive a person to order a drug online. The high cost of a medication may also attract people to these counterfeit sites that offer "the same" drug at a lower price.

The counterfeit detection device CD-3 was developed by scientists at the FDA's Forensic Chemistry Center in Cincinnati, Ohio. It is a handheld, battery-operated tool that illuminates a product with a variety of wavelengths of light.[1] Minimal technical background is needed to operate the device, as it easily provides a visual comparison of an unverified malarial drug with an authentic sample. Inspectors are able to readily identify suspicious

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products and prevent their distribution. The substandard medications compromise public health initiatives aimed at the eradication of malaria, as the drugs contain an ineffective dose or lack the active ingredient. Inadequate treatment may then lead to resistant strains of the disease. FDA Commissioner Margaret A. Hamburg, M.D, states that "Fake or substandard anti-malarial drugs cause double damage: without adequate, prompt treatment, the malaria parasite can kill a person in a matter of days, and inadequate treatment can also lead to the development of drug resistance, potentially rendering all treatment ineffective."[1]

In addition to CD-3, researchers at the University of Montreal have developed a rapid, quantitative liquid chromatography-mass spectrometry screening (LC-MS/MS) method to expose counterfeit drugs for ED.[5] The new method distinguishes 71 ED drugs and 11 natural ingredients usually found in adulterated samples in suspected products.[6] To test the potential of the LC-MS/MS, 32 pharmaceutical and natural products were analyzed and compared with the results from conventional methods.[6] Published in the Journal of Chromatography, results indicated that LC -MS/MS takes 10 minutes rather than 50 minutes required by Health Canada's current methods.[5] Furthermore, the new method identifies compounds not previously detected, even in very low concentrations. Its high success led Health Canada to it into their counterfeit monitoring process shortly after its development.[6]

With the introduction of new advancements like these, tools to globally combat counterfeit drugs and their hazards show promise. The new technology can revolutionize the effectiveness of targeting counterfeit medications and, more importantly, protect public health and safety.

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FDA- Approved Afrezza: An Inhaled Alternative to Injectable Insulin?

By: Elissa Tam, PharmD Candidate c/o 2015

Patients with Type 1 or Type 2 diabetes who cannot control their glucose levels simply by taking oral medications have to inject insulin daily. They also have to measure their glucose levels by using strips and lancets on a regular basis. For patients, especially elderly ones, the process can be bothersome and frustrating and so pharmaceutical companies are trying to find innovative ways to make insulin delivery more convenient.

As of June 29, 2014, the FDA has approved an inhaled form of insulin called Afrezza® (insulin human), designed by the drug company MannKind.[1] MannKind has been experimenting with an insulin-inhalation system that would reduce the need for injecting insulin since the company submitted a new drug application for Afrezza® back in 2010. In early 2011, the FDA rejected the drug and demanded two additional clinical trials. After completing the trials,

MannKind resubmitted Afrezza® in October 2013. Early in April 2014, the U.S. Food and Drug Administration advisory panel voted in favor of MannKind's Afrezza®. However, health regulators delayed a decision on the experimental diabetes inhalant for three months so that the FDA could review the data submitted by MannKind more carefully.[1] Finally, in late June, MannKind obtained regulatory clearance for its device.

Afrezza® is advertised as a first-in-class, ultra rapid-acting mealtime insulin therapy that comes as a drug-device combination product—inhalation powder single use dose cartridges and the small Afrezza® inhaler.[1] Earlier, there was an inhaled device called Exubera, marketed by Pfizer, that was discussed as a possible alternative to injectable insulin. However, concerns regarding a serious risk of dosing errors with Exubera (insulin is traditionally administered in international units but Exubera will be prescribed in milligrams), failure to be accepted by patients and physicians, and the development of lung cancer have Pfizer discontinuing the production of Exubera, making Afrezza® the first inhalation device for diabetes to be approved.[2]

Administered at the start of a meal, Afrezza® dissolves immediately upon inhalation and delivers insulin quickly to the blood stream. Similar to the rapid-acting insulin products that are available in the market now (e.g. insulin aspart (Novolog®) and insulin lispro (Humalog®), it should be administered 15 minutes before mealtime.[2] In Type 1 diabetics, Afrezza® would be used with injected basal insulin.[3] The FDA advisory panelists cited the advantages of more rapid onset and shorter duration of insulin action, resulting in a lower risk of hypoglycemia, in addition to greater acceptance of inhaled-insulin therapy for patients with Type 2 diabetes who refuse or are unable to self-inject insulin. It is, however, not a substitute for long-acting insulin and must be used in combination with long-acting insulin in patients with Type 1 diabetes.[4]

In an Afrezza® clinical program, which involved more than 6,500 adult patients, it was demonstrated that the inhaled insulin reduced HbA1c and resulted in less weight gain in comparison to currently available rapid-acting analogs.[5] In a pivotal trial involving 353 patients with Type 2 diabetes inadequately controlled on one or more oral agents, Afrezza® was superior to placebo in lowering HbA_{1c} at 24 weeks, with a week-24 treatment difference of -0.40 ($P<.0001$).[1] However, in another study of 344 patients with type 1 diabetes, Afrezza® had significantly inferior HbA_{1c} reduction compared with premeal injections of insulin aspart, although the difference remained within the pre-specified non-inferiority margin.[1]

In clinical trials of up to two years duration involving Type 1 and Type 2 adult patients with diabetes, any detrimental changes in lung function observed were small, did not progress, and resolved when Afrezza® treatment was discontinued.[5] Moreover, the most common respiratory side effect experienced with Afrezza® in trials was a mild, transient, non-productive cough which occurred in 27% of all study subjects and lead to treatment discontinuation in 3%.[5] A total of 4 cases of lung cancer occurred in patients who had used Afrezza®, 2 during the trial in smokers and 2 others, both squamous-cell tumors, at 2.6 and 3.8 years after the end of the trial in nonsmokers. Because of the risk of bronchospasm in patients with underlying lung disease, including chronic obstructive pulmonary disease (COPD) and asthma, Afrezza® has a black box warning advising such patients to not be used with this medication.[4] Current smokers or those who had smoked in the past are also recommended to not use Afrezza®. [1]

MannKind hopes to have the drug on the market in the upcoming months, though just how popular the inhaled device will be remains to be seen. Despite certain questionable risks and effects with the medication, Afreeza® serves as a new option for millions of Americans with diabetes by helping reduce the number of daily injections and by making controlling glucose levels more manageable.

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In Wine There Is Truth

By: Katharine Cimmino, Editor-in-Chief

Many articles and quick one-line stories have been cropping up on the internet boasting the benefits of drinking wine regularly. While headlines such as, "Drinking a Glass of Red Wine is the same as Getting an Hour of Exercise, Says New Study," may make readers ecstatic that their drinking habits are finally justified, is there any medical evidence supporting these claims?

The study In Vino Veritas is the first study to randomize people into two groups and have them consume wine. In the study, 146 healthy subjects with mild to moderate risk of atherosclerosis, according to the HeartScore®, were randomized to regular consumption of red wine (Pinot Noir) or white wine (Chardonnay-Pinot) for one year. HeartScore® is an international interactive tool that helps predict and manage the risk of heart attack and stroke in people (www.heartscore.org). Participants consumed a "moderate" (according to the World Health Organization) amount of wine each week. For men this meant 0.3L for a maximum of five times a week (0.3L is approximately 2-3 glasses of wine). For women this meant 0.2L for a maximum of five times a week (0.2L is approximately 1-2 glasses of wine). The primary endpoint was the level of HDL cholesterol at one year. Secondary endpoints included other markers of atherosclerosis (e.g. LDL cholesterol). Participates consumed their usual diet, kept log books of their activities, and had to return the corks to prove that they drank the wine and didn't sell it.[1,2]

"There may be some synergy between the low dose of ethyl alcohol in wine and exercise which is protective against CVD."

The study found that there was no difference between HDL cholesterol levels after the study concluded, however, LDL was lower in both groups at one year and total cholesterol was lower in the red wine group. Upon further analysis of the subgroups, there was a positive correlation between those who exercised regularly (at least twice a week) and wine consumption. In this group HDL cholesterol increased and LDL and total cholesterol decreased regardless of type of wine.

While at the European Society of Cardiologists Congress, Professor Taborsky (lead author of the study) said, "There may be some synergy between the low dose of ethyl alcohol in wine and exercise which is protective against CVD." He continued by stating, "In a future study we will compare the effects of red and white wine on markers of atherosclerosis in patients at high risk for CVD who take statins and do regular exercise. We hope to find that moderate wine consumption is safe in these patients."[2]

So what can we tell patients? While the results of this trial look promising, long-term studies should be conducted to see if the heart healthy effects last.

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Anticoagulation in Pregnant Women: Which Medications are Safe?

By: Diana Gritsenko, PharmD Candidate 2015

Multiple complications can arise during pregnancy. While venous thromboembolism (VTE) has a prevalence rate of just 0.06% it is one of the leading causes of maternal mortality. It is recommended that at-risk pregnant women receive anticoagulation therapy for a minimum of 3 months and VTE prophylaxis for the remaining duration of pregnancy and 6 weeks postpartum.[1] In June of 2014, a study assessed the potential of the direct thrombin inhibitor (DTI), dabigatran, and its prodrug, dabigatran etexilate mesylate, to cross the human placenta. Results showed that both formulations do cross the placenta and can therefore affect coagulation in the fetus. Thus, dabigatran should not be used in pregnant women.[2] With one drug eliminated from the arsenal, which drugs can be used in this special population?

Anticoagulants can be administered in two ways- orally and parenterally. The oral medications include DTIs, factor Xa inhibitors, and vitamin K antagonists. The use of DTIs and factor Xa inhibitors, with the exception of argatroban and fondaparinux, is not recommended in pregnancy.[1] The vitamin K antagonist, warfarin, crosses the placenta and is contraindicated in women who are pregnant (category X) unless they have a mechanical heart valve (category D). However, because of an increased risk of thromboembolism in this population, the risks associated with warfarin use (increased maternal and fetal bleeding, miscarriage, and fetal malformation) may sometimes be outweighed by the benefits. It is advised that women taking warfarin be transitioned to unfractionated heparin (UFH) or low molecular weight heparin (LMWH) 3 weeks before the planned delivery to avoid delivery trauma that can result in fetal hemorrhage.[1]

The heparins, both UFH and LMWH, are not absorbed orally and therefore must be given either intravenously or subcutaneously. Since they do not cross the placenta and do not result in fetal anticoagulation, these drugs are the anticoagulants of choice in pregnant women.[1] LMWH is preferred over UFH for all but the final weeks of pregnancy due to its more predictable pharmacokinetic profile, obviating the need for routine monitoring.[4] However, since LMWH cannot reliably be measured by activated partial thromboplastin time (aPTT), UFH is preferred in the time leading to delivery. Also, UFH is a reasonable alternative when cost is an issue or if there is a need for rapid reversal such as during delivery or perioperatively. UFH is also preferred in renal insufficiency, defined as creatinine clearance less than 30 mL/min.

If the patient has a contraindication to the use of heparins, such as a history of heparin-induced thrombocytopenia (HIT), or if the patient is unable to self-administer injections, non-heparin anticoagulants may be considered. Pregnant women can use danaparoid (not available in the United States), fondaparinux, and argatroban. Danaparoid (Orgaran®) is a low molecular weight heparinoid - a heparin derivative - that is reserved for pregnant women who have experienced acute heparin-induced thrombocytopenia.[5] Fondaparinux (Arixtra®) is a direct factor Xa inhibitor. The American College of Chest Physicians suggests limiting the use of fondaparinux during pregnancy to women who have experienced HIT and were unable to receive danaparoid. Lastly, argatroban is a parenteral DTI that is recommended for patients with HIT and renal disease. Documented use of these medications in pregnancy is only available through case reports wherein all patients had discontinued UFH/LMWH after developing HIT.[1]

It is important to note that elective cesarean delivery is not recommended for women requiring anticoagulation. Patients and their medical teams may plan for a delivery at 39 weeks (unless otherwise indicated) in order to time the discontinuation of anticoagulants.[1] The use of anticoagulants during pregnancy is challenging. There needs to be a consideration of the potential teratogenic effects, dosing complexities of the various agents, and the use of anticoagulation around the time of labor.

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New Oral Anticoagulants

By: Katharine Cimmino, Editor-in-Chief and Beatrisa Popovitz, Senior Staff Editor

Drug	Indication	Dosage	Target	Notes
Pradaxa (Dabigatran)	Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation	CrCl > 30 mL/min: 150 mg BID PO **CrCl 15 to 30 mL/min: 75 mg BID PO **NOTE: This is an FDA suggested dosing; pt's with a CrCl <30ml/min were not included in the clinical trials (RE-LY). Concomitant use of P-gp inhibitors - CrCl 30 to 50 mL/min: Consider reducing dose to 75mg BID PO if given with P-gp inhibitors dronedarone or ketoconazole. Dose adjustment is not necessary with co-administered with other P-gp inhibitors - CrCl <30 mL/min: Avoid co-administration	Factor IIa (free and clot-bound thrombin)	- Availability: 75 mg, 150mg oral capsules - Swallow capsule whole - Stop dabigatran 1 to 2 days (CrCl ≥50 mL/min) or 3 to 5 days (CrCl <50 mL/min) before invasive or surgical procedures - **BBW**: Premature d/c of dabigatran inc the risk of thrombotic events; Spinal/ Epidural hematoma - **CI**: Active bleeding, hypersensitivity to drug, mechanical prosthetic heart valve. - Pregnancy Category: **C** - **DI**: • P-gp inducers rifampin: Avoid coadministration with dabigatran • P-gp inhibitors in pt's with CrCl 30-50 mL/min: Consider reducing dose or avoid • P-gp inhibitors in pt's with CrCl <30 mL/min: Not recommended
	Treatment of DVT and PE	CrCl >30 mL/min: 150 mg BID PO		
	Reduction in the risk of recurrence of DVT & PE	CrCl <30 mL/min or on dialysis: No provided dosing recommendations Concomitant use of P-gp inhibitors CrCl <50 mL/min: Avoid co-administration		
Xarelto (Rivaroxaban)	Reduction in risk of stroke in nonvalvular atrial fibrillation	CrCl > 50 mL/min: 20 mg QD PO **with evening meal** CrCl 15-50 mL/min: 15 mg QD PO **with evening meal**	Factor Xa	- Availability: 10 mg, 15 mg, 20 mg oral tablets - 15 mg and 20 mg tablets take with food - 10 mg tablets do not need to be taken with food - Stop at least 1-2 days before surgical procedure - **BBW**: Premature d/c of rivaroxaban inc the risk of thrombotic events; Spinal/ Epidural hematoma - Pregnancy Category C - **DI**: Avoid concomitant use with: • combined P-gp and strong CYP3A4 inducers/ inhibitors • anticoagulants, NSAIDS, ASA
	Treatment of DVT or Treatment of PE	15 mg BID PO **with food** for the first 21 days ***after 21 days, transition to*** 20 mg QD PO **with food**, for remaining treatment		
	Reduction in the risk of recurrence of DVT & PE	20 mg QD PO **with food**		
	Prophylaxis of DVT following hip or knee replacement	Hip replacement: 10 mg QD PO for 35 days		
		Knee replacement: 10 mg QD PO for 12 days		

Reviewed by: Dr. H. Shafeeq

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Drug	Switching from Warfarin to Drug	Switching from Drug to Warfarin	Switching from Drug to other AC	Switching from AC to Drug
Pradaxa (Dabigatran)	D/c warfarin and start dabigatran when the INR is below 2.0	Adjust the starting time of warfarin based on CrCl - CrCl ≥ 50 mL/min, start warfarin 3 days before d/c dabigatran - CrCl 30-50 mL/min, start warfarin 2 days before d/c dabigatran - CrCl 15-30 mL/min, start warfarin 1 day before d/c dabigatran - CrCl < 15 mL/min, no recommendations can be made *Dabigatran can inc INR, the INR will better reflect warfarin's effect only after dabigatran has been stopped for at least 2 days*	Wait 12 hours (CrCl ≥ 30 mL/min) or 24 hours (CrCl <30 mL/min) after the last dose of dabigatran before initiating treatment with parenteral anticoagulant	- Start dabigatran 0 to 2 hours before the time that the next dose of the SC drug was to have been administered - Unfractionated heparin: Start dabigatran at the same time continuous infusion is d/c.
Xarelto (Rivaroxaban)	D/c warfarin and start rivaroxaban as soon as INR is below 3.0	**Option 1 [based on the package insert]:** Rivaroxaban affects INR, so using INR for initial switch may not be useful for determining the appropriate warfarin dose. One approach is to d/c rivaroxaban and begin both a parenteral anticoagulant and warfarin at the same time the next dose of rivaroxaban would be taken. **Option 2 [based on clinical data]:** Adjust the starting time of warfarin based on CrCl - CrCl ≥ 50 mL/min, start warfarin 4 days before d/c rivaroxaban - CrCl 30-50 mL/min, start warfarin 3 days before d/c rivaroxaban - CrCl 15-30 mL/min, start warfarin 2 day before d/c rivaroxaban - CrCl < 15 mL/min, no recommendations can be made *Rivaroxaban can inc INR, the INR will better reflect warfarin's effect only after rivaroxaban has been stopped for at least 1day*	If pt is transitioning to an AC with rapid onset, d/c rivaroxaban and give the first dose of the other AC (oral or parenteral) at the time that the next rivaroxaban dose would have been taken.	- Start rivaroxaban 0 to 2 hours prior to the next scheduled evening administration of drug (e.g. LMWH or non-warfarin oral AC) and omit administration of the other AC. - Unfractionated heparin: Start rivaroxaban at the same time continuous infusion is d/c.
Eliquis (Apixaban)	D/c warfarin and start apixaban when INR is below 2.0	Apixaban affects INR, so using INR for initial switch may not be useful. If continuous AC is necessary, d/c apixaban and begin both a parenteral AC and warfarin at the time of the next dose of apixaban would have been taken, d/c the parenteral AC when INR reaches an acceptable range	D/c apixaban and begin the AC at the next scheduled dose	- Start apixaban 0 to 2 hours prior to the next scheduled dose of drug (e.g. LMWH or non-warfarin oral AC) and omit administration of the other AC. - Unfractionated heparin: Start apixaban at the same time continuous infusion is d/c.

*AC= anticoagulation *INR= international normalized ratio * SC= subcutaneous *PO= by mouth *CrCl= creatinine clearance
*d/c= discontinued * BID= twice daily *QD= once daily
*dec= decrease *inc= increase * pt= patient * P-gp= P-glycoprotein

Reviewed by: Dr. H. Shafeeq

Drug	Indication	Dosage	Target	Notes
Eliquis (Apixaban)	Reduction of risk of stroke and systemic embolism in nonvalvular atrial fibrillation	5 mg taken twice a day • Give 2.5 mg BID PO if pt has any of the following 2 characteristics: age ≥ 80 years; body weight ≤60 kg; serum creatinine ≥ 1.5 mg/dL	Factor Xa	- Availability: 2.5 mg, 5 mg oral tablets - Stop at least 48 hours prior surgery with moderate or high risk of unacceptable or clinically significant bleeding. Stop at least 24 hours for procedures with low risk of bleeding (easily controlled or non-critical) - **BBW**: D/c apixaban in pt's with nonvalvular atrial fibrillation without adequate continuous anticoagulation inc risk of stroke; Spinal/ Epidural hematoma - **DI**: • Inhibitors of CYP3A4 and P-gp inc exposure to apixaban and increase the risk of bleeding. • Inducers of CYP3A4 and P-gp dec exposure to apixaban and inc the risk of stroke. • Coadministration of antiplatelet agents, fibrinolytics, heparin, aspirin, and chronic NSAID use increases the risk of bleeding.
	Prophylaxis of DVT following hip or knee surgery	2.5 mg BID PO. The initial dose should be taken 12 to 24 hours after surgery • For hip replacement surgery, continue treatment for 35 days • For knee replacement surgery, continue treatment for 12 days		
	Coadministration with CYP3A4 and P-gp inhibitors	If pt is already receiving 5 mg BID PO: • When apixaban is coadministered with drugs that are strong dual inhibitors of 3A4 and P-gp reduce dose to 2.5mg BID PO If pt is already receiving 2.5 mg BID PO, coadministration of apixaban and strong dual inhibitors of 3A4 and P-gp should be avoided.		

CLINICAL

Reviewed by: Dr. H. Shafeeq

References:

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Interview: Food and Drug Administration Pharmacist: Kimberly Defronzo

By: Melissa Roy, Co-Copy Editor [Graphics focused]

As the Consumer Safety Officer at the FDA, what does a typical day entail (or what is an unique experience that you had)?

The role of a Consumer Safety Officer is a complex and diverse one. There is no "typical" day as each day brings unexpected challenges and issues to address. One moment I can be assisting a physician trying to obtain an unapproved drug to treat a dying patient while the next moment I can be helping a manufacturer bring a drug to market. Each interaction is unique since there are nuances to every situation even if it may appears to be similar at the onset. The job is extremely demanding since it requires broad and extensive knowledge of FDA regulations as well as its policies and procedures regarding disclosure of the information. The job may be stressful but it also brings unlimited intrinsic rewards since we are in a very privileged position of being able to help someone that has exhausted all other channels.

"The job is extremely demanding since it requires broad and extensive knowledge of FDA regulations as well as its policies and procedures regarding disclosure of the information."

What did being a Reviewer for the FDA entail?

The role of a Reviewer is very different since it has a very narrow focus. When you are a Reviewer, you are responsible for reviewing only one specific area within your field of expertise. You are considered the subject matter expert (SME) for that area and your review work involves evaluating and assessing one particular section of the new drug application (NDA) or abbreviated new drug application (ANDA). Each drug application is divided into numerous sections and each subsection is assigned to the SME(s) for review and approval or rejection. The FDA implemented the "Equal Voice" initiative to ensure that, regardless of where the signatory authority resides, decisions are made only after all appropriate expertise is brought to bear. Equal Voice Initiative applies to the review of all product applications. It's an operational philosophy and set of practices to ensure that each professional viewpoint has been fully expressed, understood, and brought into the decision-making process. When there is disagreement among a review team, each discipline must voice its concerns. This process engages the entire team in scientific debate and brings each viewpoint into discussion so that a decision can be made at the team level. It doesn't mean that everyone necessarily agrees with the decision, but it ensures that all scientific and regulatory experts have input before a decision is made. The rewards of being a Reviewer comes from the fact that you are an integral contributor of the overall approval or rejection decision of a drug application.

How was one unique way that your school helped you pursue your current career path?

I strongly feel the school you select plays a crucial role in shaping your future career paths. I was very influenced by the UConn's research-based philosophy and consequently pursued my graduate studies in the pharmacy research and development field due to my professors' encouragement. I subsequently selected St. John's due to its unique offering of the "Industrial Pharmacy" program since I wanted to explore a career as a researcher at a pharmaceutical company. However, while working on my Master's thesis, I realized I did not enjoy spending countless hours in a laboratory setting so R&D was not a good fit for my personality. Therefore, I further pursued and graduated with an MBA in marketing from nearby Rutgers University. This business degree provided me with a different

insight to help me succeed in roles that are outside of the traditional pharmacy pathway of retail or hospital.

In your opinion, what course was the most beneficial towards your career and why?

It is difficult to select only one course that was the most beneficial towards my career as a pharmacist since it was a combination of many different courses that provided the sufficient knowledge to function as a pharmacist. In order to perform all of the vast responsibilities required for the role of a pharmacist, it is important to be well versed in medicinal chemistry, pharmacology, pharmacokinetics, pharmaceutics, to name a few. (Sorry to my math professor that calculus did not make my list!)

What organizations were you a member of during school; did they play any role in the career you chose to pursue?

I was in Rho Chi, however, I do not feel it contributed to any major decisions in my career choices.

Why did you decide to pursue an unconventional career path, if you could go back and start over again would you pick a different path?

I love being a pharmacist but did not enjoy being in R&D so that might be the one path I would change in hindsight.

What is the best aspect of your current job?

The ability to help people that are unable to obtain assistance anywhere else since most people tends to seek assistance from the FDA as their last resort. Therefore, the intrinsic reward from being able to help someone that has exhausted all their resources or who is in desperate need of the higher powers of the government to step in (e.g., the ability to grant access to life saving treatments) is priceless.

What is the worst aspect of your current job?

The disappointment that comes from not being able to meet the expectation of the requestor since people do not understand the limitations of the authority given to the FDA and how the FDA is strictly bounded by regulations.

Did you have a mentor? How did they help your career? If not, what is your opinion of mentors?

I was fortunate enough to have had a number of great mentors throughout my career starting with college professors, preceptors at internships/externships, and bosses at work. Having a great mentor is critical to the success of the student throughout his or her academic career and beyond. Everyone should try to place themselves in the student's position and/or try to remember back to a time when they themselves were in need of a helping hand and how important it was to be the recipient of that helping hand.

"Therefore, the intrinsic reward from being able to help someone that has exhausted all their resources or who is in desperate need of the higher powers of the government to step in"

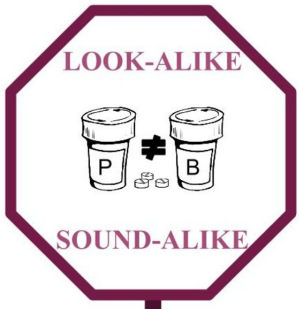
What is one piece of advice you would provide future pharmacists as they begin to look at various career options?

We are very fortunate to be pharmacists in this current market since the field of pharmacy offers us limitless opportunities and career choices. I highly suggest all students explore residencies or fellowships after graduation so that they can learn at a more in-depth level how best to match the many career choices to their personal interest and aspirations.

The Rho Chi Post wants to thank Kimberly Defronzo for sharing her time and expertise with us. We hope that this interview highlights potential career paths for our future pharmacists.

Now available at our NEWLY RE-DESIGNED website:

http://rhochistj.org/RhoChiPost/



By: Sherine Jaison
PharmD Candidate
Class of 2015

Many drugs

LOOK – ALIKE

OR

SOUND– ALIKE

causing them to be easily mixed up in practice.

Can **YOU** match these facts with the correct medication?

Answers

Matching Column: Look-Alike Sound-Alikes

1. The extended release formulation is used to prevent migraines
2. This medication has unlabeled indications for the treatment of ADHD,OCD and neuropathic pain
3. The extended release formulation of this analgesic should not be used in patients with CrCl< 30ml/min
4. Contraindicated with nitrates
5. Used for the prevention and dissolution of gallstones
6. Used in the treatment of hypertriglyceridemia and requires no hepatic and renal adjustment
7. Contraindicated in patients with second or third degree heart block
8. A short acting benzodiazepine used for preoperative sedation and for induction and maintenance of anesthesia
9. Can be used within 5 days to prevent pregnancy
10. This antiviral should be taken with meals and is used for the treatment and prevention of CMV in high risk patients

A. Ursodiol
B. Versed
C. Verapamil
D. Ulipristal
E. Ultram
F. Valganciclovir
G. Valproic acid
H. Vardenifil
I. Vascepa
J. Venlafaxine

Lexi-Comp OnlineTM , Lexi-Drugs OnlineTM , Hudson, Ohio: Lexi-Comp, Inc.; January 1st, 2014

How Did You Do???

Answers to Crossword & Look Alike and Sound Alike

A. 5 B. 8 C. 7 D. 9 E. 3 F. 10 G. 1 H. 4 I. 6 J. 2

Quote of the Month

By: Melissa Roy, Co-Copy Editor [Graphics focused]

Do you enjoy our puzzles?

Send us a suggestion for a brainteaser at

RhoChiPost@gmail.com

We will feature your work in our next issue!

RHO CHI POST: TEAM MEMBERS

EDITORS

@ Katharine Cimmino ***(6th Year, STJ; Editor-in-Chief)***
I have always been an avid reader and writer. As a member of the Rho Chi Post I am able to merge my passions with the professionalism that comes with aspiring to be a healthcare provider. I am eager to be a part of a publication that promotes my interests and vocation.

@ Bharat Kirthivasan ***(PhD, Co-Copy Editor [Content-Focused])***
I am a doctoral candidate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.

@ Hayeon Na ***(6th Year, STJ; Co-Copy Editor [Content-Focused])***
Hello! My name is Hayeon Na. I am a 2015 PharmD Candidate and one of the Copy Editors for the Rho Chi Post. I hope the information I present will be helpful, or at least interesting. If you have any comments regarding my contribution, feel free to contact me at any time!

@ Tasnima Nabi ***(5th Year, STJ; Co-Copy Editor [Content-Focused])***
Writing has always been my greatest outlet for experience and knowledge, through which I hope to keep you engaged and informed. It is imperative to keep up with our changing profession and community, and I look forward to bringing pertinent information to the newsletter.

@ Erica Dimitropoulos ***(6th Year, STJ; Co-Copy Editor [Content-Focused])***
As busy student pharmacists, we often fail to keep current with healthcare developments. My aim is to sort through the news and provide quick updates that are important to our profession. Feel free to contact me if there are any topics you would like to see covered in the next issue!

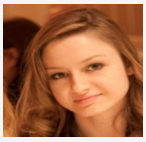
@ Melissa Roy ***(6th Year, STJ; Co-Copy Editor [Graphics-Focused])***
We as future healthcare professionals owe it to our patients and ourselves to be aware and current on the events affecting our profession. The Rho Chi Post is our way to learn new things and stay in touch with the pharmacy world, on- and off-campus. Feel free to reach out to me with suggestions and comments.

RHO CHI POST: TEAM MEMBERS

@ Tamara Yunusova ***(4th Year, STJ; Senior Staff Editor)***
My name is Tamara Yunusova, and I am a 3rd year Pharm D candidate at St. John's University. I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.

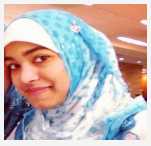
@Davidta Brown ***(4th Year, STJ; Senior Staff Editor)***
My two great loves are innovative science and quality writing, and the Rho Chi Post is an insightful combination of both. As an editor, I look forward to bringing relevant information and fresh perspectives to the student and faculty of St. John's University, as well as to making the Rho Chi Post a newsletter that offers something new to every reader.

@ Beatrisa Popovitz ***(6th Year, STJ; Senior Staff Editor)***
I am eager to relay current information on interesting topics making waves in the world of healthcare pertinent to the advancement of our profession. As student pharmacists, we are molding the future of our profession, and the Rho Chi Post facilitates the cultivation of a relationship (between students, faculty, and other members of the healthcare community) to share ideas and spread awareness of various issues.



@ Ada Seldin ***(6th Year, STJ; Staff Editor)***
I am thrilled to have become a new member of the Rho Chi Post team. I hope to further strengthen the goals of this newsletter and make a lasting contribution. It is important, as future pharmacists, to collaborate with our peers, as well as accomplished professionals in the field. Rho Chi Post provides a vehicle to voice our opinions and share relevant news.

@ Sang Hyo Kim ***(3rd Year, STJ; Staff Editor)***
Advancements of technology and developments of new medicines, prolonging the lifespan and improving the quality of life, have increased the geriatric population. In years to come, pharmaceutical industries and healthcare systems will persistently work to find solutions to changing demands and new problems of the society. Through the Rho Chi Post, I wish to learn, educate, and prepare myself and others for the future.



@ Fatema Elias ***(5th Year, STJ; Staff Editor)***
I am honored to be a part of the Rho Chi Post team. In this age of technology and the continuously changing healthcare profession, I hope to engage like-minded students and professionals. Writing is something that I hold dear to my heart and I hope with this newsletter we can all stay well informed, interested, and educated.

@ Azia Tariq ***(4th Year, STJ; Staff Editor)***
The Rho Chi Post is a prominent and highly esteemed resource for pharmacy students and professionals. I am privileged to be a part of the team and hope to contribute informative and engaging pieces to the newsletter.

@ Sherine Jaison ***(6th Year, STJ; Staff Writer)***
I find the Rho Chi Post extremely informative and am eager to join the team. I hope my articles will enlighten you about the recent developments in the field of pharmacy and will help you to be a well-informed healthcare provider.

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@ You!
We are always looking for creative and motivated students to join our team!
If you are interested in becoming an editor for the Rho Chi Post, please visit:
http://rhochistj.org/RhoChiPost/EditorApplication

EDITORS

RHO CHI

The Rho Chi Society encourages and recognizes excellence in intellectual achievement and advocates critical inquiry in all aspects of Pharmacy.

The Society further encourages high standards of conduct and character and fosters fellowship among its members.

The Society seeks universal recognition of its members as lifelong intellectual leaders in Pharmacy, and as a community of scholars, to instill the desire to pursue intellectual excellence and critical inquiry to advance the profession.

THE RHO CHI POST

MISSION

The Rho Chi Post is a monthly, electronic, student-operated, faculty-approved publication that aims to promote the pharmacy profession through creativity and effective communication. Our publication is a profound platform for integrating ideas, opinions, and innovations from students, faculty, and administrators.

VISION

The Rho Chi Post aims to become the most exciting and creative student-operated newsletter within St. John's University College of Pharmacy and Health Sciences. Our newsletter continues to be known for its relatable and useful content. Our editorial team continues to be known for its excellence and professionalism. The Rho Chi Post essentially sets the stage for the future of student-operated publications in pharmacy.

VALUES

Opportunity, Teamwork, Respect, Excellence

GOALS

1. To provide the highest quality student-operated newsletter with accurate information
2. To maintain a healthy, respectful, challenging, and rewarding environment for student editors
3. To cultivate sound relationships with other organizations and individuals who are like-minded and involved in like pursuits
4. To have a strong, positive impact on fellow students, faculty, and administrators
5. To contribute ideas and innovations to the Pharmacy profession

CURRENT EXECUTIVE BOARD

Anthony, Tyler, Sara, Tasnima, Joshua, Fawad at the 2014 Induction Ceremony

President: **Tyler Valente**
Vice President: **Fawad Piracha**
Secretary: **Tasnima Nabi**
Treasurer: **Anthony Nania**
Historian: **Sara James**
Media Relations Coordinator **Joshua Bliss**
Faculty Advisor: **S. William Zito, PhD**

UPCOMING EVENTS

Dec 7-11: ASHP Midyear
Anaheim, CA

Dec 11-17: Finals Week
St. John's University

Feb 27– 28: Pharmacy Ownership Workshop
Memphis, TN