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RHO Rx CHI post

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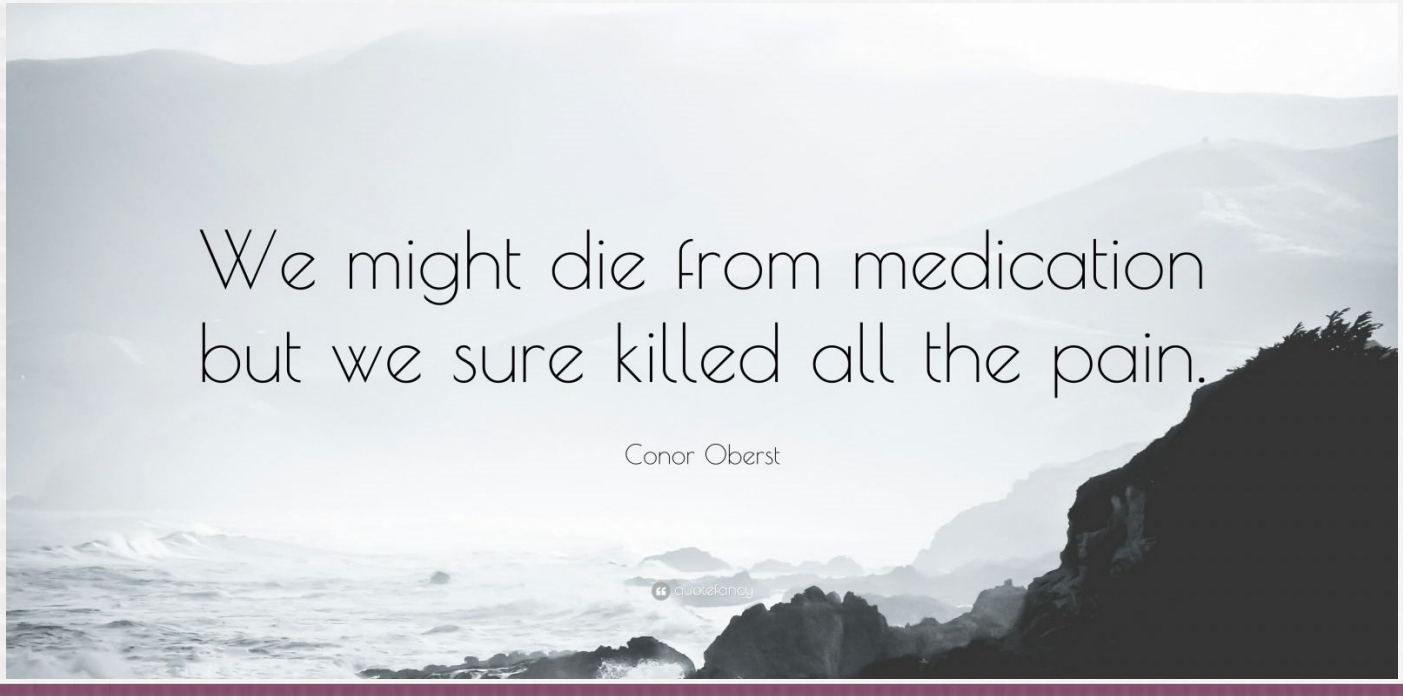
By: Matthew Kahn, Graphics Editor



Pharmacy Lobby Day 2017, a student's perspective

By: Zachary Reale, PharmD Candidate c/o 2018

Every April, pharmacists and pharmacy students from all across New York State gather in Albany for Pharmacy Lobby Day. The event, organized by the Pharmacists Society of the State of New York (PSSNY), is held in collaboration with many other New York State pharmacy associations including the Student Pharmacists Society of the State of New York (SPSSNY). The day is an opportunity for pharmacists and future pharmacists to meet with the state legislative body and discuss laws and regulations that affect the profession on a daily basis. It is a unique chance to advance the field of pharmacy as well as build relationships with fellow professionals.

The day takes place at the state's Capitol Hill and starts off in the performing arts center known as 'The Egg." After a welcome by the leaders of PSSNY, legislative experts briefed the pharmacy lobbyists on each bill, highlighting key points and healthcare benefits. It was a time for everyone to be brought up to speed on the issues at hand and ask any questions regarding the year's potential new laws. Tips and pointers for speaking with politicians were also given to help out any first-time attendees. Afterwards, preassigned teams of students and pharmacists met one another for the first time and then it was off to meet the legislators. This year, there were three specific bills on the agenda. The first bill, if passed, would authorize registered pharmacy interns to administer vaccines to adults. Most importantly, this initiative would help train student pharmacists more effectively. It would ensure that newly graduated New York pharmacists would be as marketable as students from the other 46 states that already allow registered pharmacy interns to administer vaccines.

The second bill would expand the vaccines administered by pharmacists to include all CDC-recommended vaccines for adults. This would help improve patient accessibility to important vaccinations, especially in medically underserved areas such as rural upstate and western New York. Additionally, this would be a huge leap forward in promoting public health by increasing adult immunization rates for Tdap, influenza, pneumococcal and HPV vaccines.

The third bill would require pharmacy technicians to be registered and certified as well as establish educational requirements for them. In a state that currently has no direct jurisdiction over pharmacy technicians, this legislation is much needed. Above all it would protect the public from mistakes made within the pharmacy due to insufficient training or unqualified staffing. Technicians would be held accountable for actions when dealing with controlled substances and would have to meet minimum education requirements.

All three bills would significantly improve the practice of pharmacy in New York State. It was up to the students and pharmacists at Pharmacy Lobby Day to share meaningful stories and experiences in hopes of conveying the importance of passing each bill. It was crucial to demonstrate the positive impact that each bill would have on, not only the pharmacy profession, but also on the health and safety of the public.

Only time and the vote of each legislator will determine which bills will be passed into law and which bills will be put back to be lobbied again next year. No matter the case, Pharmacy Lobby Day will always be a success. It is an incredible opportunity for both seasoned pharmacists and student pharmacists to advocate on behalf of the profession of pharmacy. Most of all, it is an event that should be attended by all pharmacy students across the state and serves to only benefit the pharmacy profession.

Each year in April the College of Pharmacy sends out an informational email to all years of Pharmacy students. There is no cost to attend and the school provides a bus for all students going. Many pharmacy organizations also advertise the event and encourage members to attend. Attending this event will only improve your experience as a future pharmacist and it is a great way to get involved. Be on the look out for next year's e-mail!

Pharmacy Pearls: Current treatment for hepatitis C

By: Vicky Liu, PharmD Candidate c/o 2018

Hepatitis is an inflammation of the liver commonly caused by viruses which can lead to self-limitation, fibrosis, cirrhosis, or liver cancer. Viral hepatitis is categorized into five types: A, B, C, D, and E. Of the five types, A, B, and C are the most prevalent in the United States. The Centers of Disease Control and Prevention (CDC) reported that there were 1,239 acute cases of hepatitis A virus (HAV), 2,953 acute cases of hepatitis B virus (HBV), and 2,194 acute cases of hepatitis C virus (HCV) in 2014. Out of the three, HCV is the most virulent. In 2014, 19,659 death certificates listed HCV as the primary cause of death compared to 76 and 1,843 for HAV and HBV, respectively.[1]

Hepatitis C is further classified into genotypes based on the virus's nucleotide sequence. There are six major genotypes of which genotypes 1, 2, and 3 are the most prevalent out of the six. The prevalence of each genotype may differ in each country. For example, genotype 1 is predominant in the United States and Europe, genotype 4 is seen in North Africa and the Middle East, and genotype 5 and 6 are only prevalent in Hong Kong and South Africa.[2] The mechanism behind HCV's genotypic diversity is due to its RNA polymerase. Because HCV contains a RNA-dependent RNA polymerase, it does not have any means to correct errors in the new, complementary strand during replication, leading to rise of various genotypes.

Unfortunately, there are no vaccines available for HCV. However, there are four different classes of direct acting antivirals (DAAs) to treat and potentially cure hepatitis C. The DAAs are nonstructural protein 3/4A (NS3/4A) protease inhibitors, nucleoside nonstructural protein 5B (NS5B) polymerase inhibitors, non-nucleoside NS5B polymerase inhibitors, and nonstructural protein 5A (NS5A) inhibitors. These four classes target HCV's lifecycle and affect essential proteins used for viral replication. For example, within HCV, there are structural and nonstructural proteins that help the virus in survival. Structural proteins are important in providing RNA binding, cell signaling, cell growth, and survival. Nonstructural proteins are utilized for replication, RNA transcription, post-translation, assembly, and attachment to hosts.[3]

NS3 is a nonstructural, multifunctional protease containing a helicase domain linked to a protease domain. NS3 with its cofactor NS4A cleaves polyproteins at four sites to produce proteins for replication and survival. NS3 also has a role in blocking host immune cell signaling. By targeting NS3/4A at its active site, these protease inhibitors prevent viral replication and promote antiviral signaling. Grazoprevir, paritaprevir, and simeprevir are examples of this class.[4]

NS5B is a polymerase which initiates RNA synthesis by forming a phosphodiester bond between the priming and initiating nucleotides. This early product is used as a primer to which additional nucleotides are added on. At this point, NS5B continues to add on nucleotides without dissociating from the chain. This inherent mechanism renders the polymerase vulnerable, which led to the development of three classes of NS5B polymerase inhibitors including nucleoside inhibitors (NIs), non-nucleoside inhibitors (NNIs), and pyrophosphate (PPi) analogs. PPi compounds are toxic, which limits their use for treatment and are employed as salvage therapy. NIs have been used to treat HBV, herpes viruses, and human immunodeficiency virus (HIV). NIs are prodrugs and are unionized, allowing them to penetrate the virus's cell membrane. Next,

they undergo phosphorylation to pose as nucleotides which NS5B collects and adds onto its chain of nucleotides. However, the incorporated NIs are non-functional, which causes the nucleotide chain to terminate—disabling viral replication. Sofosbuvir is the only nucleoside NS5B polymerase inhibitor available for treatment of HCV. On the other hand, NNIs work by binding allosterically to NS5B, causing a conformational change in the polymerase preventing further elongation of nucleotides. Dasabuvir is the only approved NNI.[5]

NS5A is a protease involved in RNA replication, RNA translation, and packaging. However, its exact mechanism for these processes is not well understood. These inhibitors affect viral genome replication and the assembly and release of virions but it is unclear where they target within the NS5A. Examples of NS5A inhibitors are daclatasvir, ledipasvir, ombitasvir, elbasvir, and velpatasvir.[6]

Although treatment for hepatitis C has been improved, there are many individuals who are unable to access care. According to the World Health Organization (WHO), in 2015, 71 million people were infected with HCV but only 14 million (20%) knew of their diagnoses. Of the 14 million, 1.1 million (7.4%) were treated.[7] WHO implemented an annual World Hepatitis Day on July 28 to spread awareness and campaign to eliminate viral hepatitis.[8]

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Guidelines have incorporated the use of these novel agents for initial treatment of HCV. Below is a simplified table of current recommendations by the American Association for the Study of Liver Diseases.

Initial Recommended Treatment for HCV in Treatment-naïve Patients Without Cirrhosis[9-17]						
Drug	Frequency	Duration	Genotype	Special Considerations	Monitoring	Clinical Pearls
Elbasvir 50 mg and Grazoprevir 100 mg (as **Zepatier**®)	Once daily	12 weeks	1a, 1b, 4	With or without food	Must confirm absence of NS5A resistance associated substitutions at baseline for genotype 1a Test patients for prior or current HBV ALT (baseline, week 8, and as needed thereafter)	Not recommended to be co-administered with moderate to strong 3A inhibitors ***Contraindications***: Moderate to severe hepatic impairment (Child-Pugh B or C)
Ledipasvir 90 mg and Sofosbuvir 400 mg (as **Harvoni**®)	Once daily	12 weeks	1a, 1b, 4, 5, 6	With or without food	Test patients for prior or current HBV	Non-black patients, HIV-uninfected and HCV RNA level <6 million IU/mL are treated for 8 weeks Avoid amiodarone– due to severe bradycardia especially taken with β-blockers or in patients with cardiac co-morbidities Use of P-glycoprotein inducers not recommended due to decreased plasma concentrations No dose can be recommended for end stage renal disease (ESRD)

Drug	Frequency	Duration	Genotype	Special Considerations	Monitoring	Clinical Pearls
Paritaprevir 150 mg, Ritonavir 100 mg, and Ombitasvir 25 mg	+ Dasabuvir 600 mg ***once daily*** (as extended-release) [as **Viekira XR®**] ± weight-based Ribavirin**	12 weeks	1a, 1b (exclude ribavirin for 1b)	Taken with a meal. Fasting will cause reduced virologic response and possible resistance Avoid consumption of alcohol within 4 hours before or after administration of extended-release tablet	Hepatic lab testing during first 4 weeks and check for ALT elevations Test patients for prior or current HBV	***Contraindications***: Moderate to severe hepatic impairment; highly dependent CYP3A substrates; moderate to strong inducers of CYP3A; strong inhibitors or inducers CYP 2C8
	+ Dasabuvir 250 mg ***twice daily*** [as **Viekira Pak®]** ±weight-based Ribavirin		1a, 1b (exclude ribavirin for 1b)			
	+ weight based ribavirin		4		(Ribavirin) Pregnancy testing-avoid in pregnant women and male partners of women who are pregnant; hemolytic anemia	

**Weight-based ribavirin = 1000 mg/day for patients ≤75 kg and1200 mg/day for those >75 kg, divide daily dose twice daily and administer with food

Drug	Frequency	Duration	Genotype	Special Considerations	Monitoring	Clinical Pearls
Simeprevir 150 mg (as **Olysio®**) + Sofosbuvir 400 mg (as **Solvadi®**)	Once daily		1a, 1b	Simeprevir requires to be taken with food	Baseline hepatic panels Test patients for prior or current HBV	Rash, photosensitivity, serious bradycardia when taken both amiodarone and this combination therapy Dose recommendation cannot be made for ESRD or severe renal impairment
Sofosbuvir 400 mg and Velpatasvir 100 mg (as **Epclusa®**)	Once daily		1a, 1b, 2, 3, 4, 5, 6	With or without food	Test for current or prior HBV prior to initiation	Avoid amiodarone with Epclusa – serious symptomatic bradycardia Interacts with P-gp inducers and/or potent CYP inducers (decrease concentrations of sofosbuvir and/or velpatasvir)
Daclatasvir 60 mg (as **Daklinza®)** + Sofosbuvir 400 mg (as **Sovaldi®)**	Once daily		1a, 1b, 3	With or without food	Test patients for prior or current HBV	Symptomatic bradycardia with amiodarone and combination therapy – avoid Decrease dose for daclatasvir when used with P450 3A/4 inhibitors ***Contraindications*:** (Daclatasvir) CYP3A strong in-

Refer to full prescribing info for each respective drug for more details. This highlights certain points for each regimen

All treatments have a black box warning for the risk of reactivating HBV in patients co-infected with both HBV & HCV

Valbenazine (Ingrezza®): The first FDA approved drug for tardive dyskinesia

By: Yan Yi Chan, PharmD Candidate c/o 2018

Tardive dyskinesia is a movement disorder characterized by involuntary and repetitive movements of the tongue, jaw, lips, face, trunk, upper and lower extremities, and respiratory system.[1] This is usually associated with the use of dopamine receptor blockers such as antipsychotic medications in treating psychiatric disorders and antiemetic medications, such as metoclopramide, in treating symptomatic gastroesophageal reflux.[1] Even though the risk of developing tardive dyskinesia is lower with the newer atypical antipsychotics as compared to the first generation antipsychotics, this condition can still develop in some patients with long term use.[2] Unfortunately, tardive dyskinesia is often irreversible and can have significant effects on a patient's functioning. It can cause speech impairment, difficulties in chewing and swallowing, and increase the risk of falls.[3] Because of the public perception of these involuntary movements, patients with this condition may feel shameful, depressed, or socially isolated. Treating tardive dyskinesia can be challenging. Discontinuing or lowering doses of antipsychotics is sometimes not an option because it can exacerbate tardive dyskinesia symptoms or worsen a patient's psychiatric condition. Symptoms of tardive dyskinesia often are still present even with the discontinuation or dose reduction of the offending drug. Increasing doses of antipsychotics may reduce or mask the involuntary movements initially, but can worsen tardive dyskinesia in the long run.[4] However, hope has arrived for patients with tardive dyskinesia with the FDA approval of a new drug – valbenazine (Ingrezza®).

On April 11, 2017, the FDA approved of the first drug indicated for the treatment of tardive dyskinesia.[5] Valbenazine is a reversible and selective vesicular monoamine transporter 2 (VMAT2) inhibitor. VMAT2 is a protein present in neurons that regulates the packaging of dopamine and other monoamines from the cytoplasm into vesicles for storage and release into the synapse. Valbenazine reduces the amount of dopamine that is released into the synapse by modulating dopamine transport into the vesicles. As a result, there is less stimulation of the postsynaptic dopamine receptors in the nigro-striatal pathway, thus reducing the degree and intensity of the involuntary movements.[1]

The phase 3 trial of valbenazine was a randomized, double blind, placebo controlled, parallel group, and fixed dose study that was 6 weeks in duration.[6] It enrolled 234 patients age 18 to 85 who were medically stable and were diagnosed according to DSM-IV criteria with schizophrenia, schizoaffective disorder, or mood disorder for 3 months or more prior to screening. Of the 234 patients, 66% were diagnosed with schizophrenia or schizoaffective disorder while the remainder of the patients had a mood disorder. Patients also had to be diagnosed with moderate to severe tardive dyskinesia for 3 or more months prior to screening. Patients were allowed to continue the use of medications for their psychiatric and other medical conditions, but had to have been stable on their medications for at least 30 days prior and could not make changes in therapy during the length of the study. Patients were randomized to receive either placebo, valbenazine 40 mg once daily, or valbenazine 80 mg once daily. The primary efficacy was change in the Abnormal Involuntary Movement Scale (AIMS) dyskinesia score for items 1-7 from baseline to week 6. An AIMS response was defined as achieving at least a 50% reduction from baseline in dyskinesia score. The patients were video recorded at each study visit at baseline and weeks 2, 4 and 6. They were reviewed by neurologists who specialize in movement disorders and were blind to treatment and study visit sequence. Patients were also evaluated for vital signs, physical examinations, ECG, laboratory tests, psychiatric or mood status, and suicidal ideation or behavior, in which there were no clinically relevant changes observed throughout the entire length of the study. Improvements in AIMS dyskinesia score was observed in both treatment groups within 2 weeks of initi-

ating treatment. From baseline to week 6, the changes in AIMS dyskinesia score were -3.2 in the 80 mg group and -1.9 in the 40 mg group compared to -0.1 in the placebo group. At week 6, 40% of the 80 mg group and 23.8% of the 40 mg group had an AIMS response compared to 8.7% in the placebo group. The common side effects observed were somnolence, akathisia, and dry mouth. The number needed to treat (NNT) in the 80 mg group was 4 while the number needed to harm (NNH) was 13; the NNT in the 40 mg group was 7 and NNH was -32. This suggests that the benefits of valbenazine may outweigh the risks.

The dosing of valbenazine is 40 mg once daily initially for 4 weeks, then increase to 80 mg once daily. Patients can also be continued on 40 mg daily if needed. Use of valbenazine with a strong CYP3A4 inducer or monoamine oxidase inhibitor is not recommended. If coadministered with a strong CYP3A4 inhibitor, reduce the dose of valbenazine to 40 mg once daily. Dose reduction should be considered if coadministered with a strong CYP2D6 inhibitor. Dose reduction is not necessary in the elderly or patients with renal impairment. However, use should be avoided in patients with severe renal impairment (creatinine clearance less than 30 mL/min). In patients with moderate or severe hepatic impairment (Child-Pugh score 7 to 15), the recommended dose is 40 mg once daily.[7] In addition, valbenazine may cause QT prolongation but the degree of it is not clinically significant with the recommended dosing.[1]

Valbenazine improved tardive dyskinesia regardless of the antipsychotic drug patients were using, psychiatric diagnosis, and severity of tardive dyskinesia.[1] It was well tolerated during the clinical trials and patients' psychiatric status were stable while using valbenazine.[6] This drug is very promising for patients with tardive dyskinesia, especially for those where switching or discontinuing the antipsychotic drug is not possible.

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FDA approves edaravone (Radicava™) to treat ALS

By: Thanesha Graham, PharmD Candidate c/o 2019

Amyotrophic lateral sclerosis (ALS) is commonly referred to as Lou Gehrig's disease. Gehrig was an American first baseman who played 17 seasons in Major League Baseball for the New York Yankees and passed away from ALS at the age of 37. According to the Centers for Disease Control and Prevention, approximately 12,000-15,000 Americans have ALS, a rare paralyzing disease.[1] ALS destroys the nerve cells that control voluntary muscles responsible for chewing, walking, breathing and talking.[1] Individuals with ALS struggle with these normal bodily functions because their nerves lose the ability to activate specific muscles.[1] These inactivated muscles become weak and soon after, paralyzed. ALS is a progressive disease with a grim prognosis because individuals become worse overtime. Eventually, people who suffer from Lou Gehrig's disease die from respiratory failure three to five years from the first onset of symptoms.1 The mean age of onset is 56 years in individuals with no known family history and 46 years in individuals with more than one affected family member.[2] Genetic testing plays a large role in the diagnosis of this disease because ALS can be inherited through a variety of ways including autosomal dominant, autosomal recessive, or X-linked genes.

Edaravone (Radicava™) is the first new drug approved by the FDA to treat ALS in 20 years.[1] Edaravone was initially widely used in Japan under the name Radicut® marketed by Mitsubishi Tanabe Pharma Corporation. After the United States worked with the Japanese drug developer and filed a marketing application, the treatment became available for use in the States.[1] Edaravone is an intravenous infusion that must be administered by a health care professional.[1] This drug is accompanied by a very specific dosing schedule, with an initial treatment cycle of daily dosing for 14 days, followed by a 14-day drug-free period and further cycles of dosing for 10-14 days followed by another 14 days drug-free.[1] Edaravone was proven to be efficacious after a six-month clinical trial in Japan called "Study of MCI- 186 for Treatment of Amyotrophic Lateral Sclerosis in Japan".[1] After 24 weeks of treatment, individuals who received the drug declined less than those receiving placebo.[1] The adverse reactions observed with Radicava were bruising and gait disturbances.[1] There were also some serious risks associated with the drug requiring immediate care which included hives, swelling, shortness of breath, and allergic reactions to an ingredient in the drug, sodium bisulfite.[1] Although the drug has substantial benefits, it may not be a perfect fit for all ALS patients, due to the risks and adverse effects. In fact, sodium bisulfite may cause anaphylactic symptoms that are life threatening and possibly fatal.[1]

Before edaravone, riluzole (Rilutek®) was the only other FDA-approved drug for ALS. Two other drugs such as tricyclic antidepressants and anti-cholinergics are used to reduce oral secretions in certain patients.[2] These drugs are used because patients with bulbar-type symptoms, named after the corticobulbar neurons affected by ALS, experience dysarthria and dysphagia.[2] Additionally, baclofen and benzodiazepines are used to relieve spasms and muscle cramps.[2] Edaravone works uniquely by reducing oxidative stress, one of the factors that contributes to the onset and progression of the disease. Patients with ALS show increases in oxidative stress biomarkers, which serves as a useful target for novel ALS drugs.[3] Oxidative stress is the imbalance between the production of free radicals and the ability of the body to counteract or detoxify their harmful effects.[3]

Although treatment for Lou Gehrig's disease is palliative, drugs such as edaravone help manage its life-altering symptoms. The development of this drug is a major step in finding stronger, more effective drug therapies for this fatal disease.

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Ketogenic diets for diabetes mellitus and obesity

By: Anna Chen, PharmD Candidate c/o 2020

Every day the public faces an onslaught of a new fad diet that promises to prevent boredom and the feelings of restriction that regular diets are famous for. One example is the banana diet that promises to keep one satiated with the high volume and fiber content of bananas to kill cravings for unhealthy snacks. Some followers have taken this diet to the extreme of eating only bananas to quickly reduce weight. However, one famous fad diet, the Atkin's Diet, has shown great potential to be a primary option of therapy for patients suffering from obesity or diabetes. The Atkin's Diet is a type of ketogenic diet that focuses on a low carbohydrate and high protein and fat intake to induce the body to utilize ketosis to burn fat when the supply of readily available carbohydrates is low. There is evidence that the unique aspects of drastically reducing carbohydrate intake help patients with glucose metabolism and decrease lipid levels more so than traditional low calorie diets that do not restrict carbohydrate intake. When used appropriately, ketogenic diets have shown to be safe to use and tolerable in addition to being more effective than traditional low calorie diets.

A controlled study of 9 lean men placed on a ketogenic diet for 4 weeks, showed a 15% reduction in blood glucose and 30% reduction in whole body glucose metabolism.[1] Since the bulk of the experiment diet consisted of protein and fats, meals were prepared with chicken breast, tuna fish, eggs, cheddar cheese, ground beef, sour cream, cream cheese, and mayonnaise.[1] Thus, the sources of protein and fat in ketogenic diets are still chosen in a health conscious way in that dieters would still stray away from trans fats and unhealthy junk food. However, the main pillar of such ketogenic diets are reducing carbohydrate intake to less than 20g per day. Studies were then made to see whether it was ketosis, the burning of fat over carbohydrates, that was responsible for the beneficial effects of ketogenic diets. One study hypothesized that ketosis was responsible for a reduced hepatic glucose output in patients with Type 2 diabetes when placed on ketogenic diets. The study observed 13 obese Type 2 patients over 6 weeks with two diets of equal caloric intake and high protein intake (55%) but different carbohydrate intake. One of the diets incorporated a low amount of carbohydrates and the other a high amount of carbohydrates to induce high levels of ketosis and low levels of ketosis respectively.[1] Overall even with similar weight loss, the low carbohydrate diet had beneficial effects of lowered blood glucose, better glucose tolerance without affecting plasma insulin, and faster decrease in hepatic glucose output. With the only difference being that the diet having lower carbohydrates and therefore higher levels of ketosis activity indicates that the effects of ketosis and low carbohydrate intake are crucial in improving glucose metabolism in patients regardless of weight loss.

A study of 64 obese subjects all having a body mass index (BMI) greater than 30 were divided into two groups based on whether they had a normal blood glucose levels (5.127 ± 0.440 mmol/l) or high blood glucose levels (10.481 ± 3.026).[2] Both groups were put on the same ketogenic diet for 56 weeks. Similar to the previously mentioned studies, the group with high blood glucose levels observed fasting blood glucose levels decreased from 10.481 ± 3.026 mmol/l to 4.874 ± 0.556

mmol/l;[2] thus, solidifying ketogenic effects on high blood glucose. The levels of HDL cholesterol were shown to increase from 1.033 ± 0.264 mmol/l to 1.586 ± 0.211 mmol/l and levels of LDL cholesterol decreased from 5.160 ± 0.892 mmol/l to 3.379 ± 0.608 mmol/l.[2] These results put the subjects at a lower risk of cardiovascular disease as well as events such as myocardial infarctions. Similar increase in HDL and decrease in LDL were shown in those with normal blood glucose levels and with relatively no change in blood glucose levels in the same patients.[2] The unchanged glucose levels in the group with normal blood glucose levels calls into question the claim that diets low in carbohydrates and high in fat may be harmful and induce insulin resistance. The lowered risk of cardiovascular disease is strongly correlated from the changed body composition as subjects showed "a preferential loss of fat mass and preservation of lean body mass following the administration of ketogenic diet."[2]

In regards to the safety and tolerability of ketogenic diets, a study in Spain was done on 89 patients with Type 2 Diabetes in a randomized weight loss intervention program that included lifestyle support to compare the effects of a very low carbohydrate-ketogenic diet (VLCK) as compared to a standard low calorie (LC) diet. The study extended for a period of 4 months and showed that the VLCK group showed more significant improvements in weight loss, insulin sensitivity, triglyceride levels, and HbA1c levels than the LC group.[3] Since a main pillar of the ketogenic diet consists of large protein intake, there are concerns that the high protein content would exacerbate patients with albuminuria or nephropathy to renal failure. Although the exact macro nutrient goals of patients with diabetes are yet to be known, the 30-53% protein in the daily ketogenic patient diet showed no negative effects on albuminuria nor on plasma creatinine levels within the 4 month period.[3]

The one possible drawback identified in the Spain study was the 80% of the VLCK patients reporting mild adverse events compared to only 41% of the LC patients.[3] The mild adverse events consisted of headache, nausea, orthostatic hypotension, and constipation.[3] However, more patients were able to stick through the VLCK diet to the end compared to the LC diet and 92.5% of VLCK patients deemed the program satisfactory compared to just 68.5% of the LC patients.[3] A similar study comparing the effects of traditional low calorie vs. low carbohydrate in patients with Type 2 diabetes in Kuwait found a low carbohydrate diet to give more significant benefits but recommended that patients be placed on strict medical supervision as glucose levels start decreasing in patients.[4] The same study found that physicians were able to decrease anti-diabetic medications in patients on the low carbohydrate diet due to better glycemic control.[4] Thus, in addition to the previous study that extended for 56 weeks, a ketogenic diet is acceptable for both short and long term use in patients with diabetes.

Contrary to the previous three studies mentioned, a ketogenic diet can be utilized as a treatment plan without extensive observation or doctor visits. An online intervention study randomized 25 patients with type 2 diabetes into a ketogenic diet (n=12) or a standard low fat diet (n=13) for 32 weeks.[1]

Through patient self-reporting, researchers found no statistically significant signs of diabetes related distress nor depressive symptoms within the two groups.[1] However, patients in the ketogenic diet reported that they would be less likely to cheat on their diets compared to those in the standard diet and gave high ratings in categories including better attitudes on the ketogenic diet and beneficial outlooks to their improved physical

health.[1] Not unlike the studies previously described, the online intervention study found more significant results in the ketogenic diet compared to the standard diet that include reduced HbA1c levels, greater weight loss, and reduced triglycerides.[1] The limitations to online studies and patient self-reporting notwithstanding, the data obtained and particularly its congruence with evidence from the other studies, asserts that ketogenic diets are a substantial form of therapy.

The win-win situation with both improved glucose metabolism and decreased triglyceride levels from a ketogenic diet is phenomenal for treating patients suffering from obesity or diabetes. A ketogenic diet is also compatible with regular medications as the patients in the online intervention study were still on prescribed metformin while on the ketogenic diet. Only one patient experienced an adverse event due to hypoglycemia from taking a dose of metformin.[5] Moreover, the ketogenic diet does not have to be a permanent lifestyle commitment as the patients in the Goday A, Bellido D, Sajoux I, et al. study were transitioned to a less restrictive lifestyle with nutritional counseling after reaching weight loss goals.[3] This novel diet is an answer to the call for a diet that is more effective than standard diets in granting long term results while being satisfying enough to keep patients both interested and committed to a form of therapy.

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Do you attend events on campus, but you prefer not to write?

SUBMIT YOUR PHOTOGRAPHS

Send them to our editors at RhoChiPost@gmail.com

and we will feature your pictures in our next issue!

The prior authorization process and its effect on patient care

By: Zachary Reale, PharmD Candidate c/o 2018

Today there are over fifty oral anticancer agents on the market and the Food and Drug Administration (FDA) have approved much of these agents within the last ten years. The number of oral anticancer agents will likely continue to grow in the near future, as more than 25% of developing anticancer agents are oral formulations.[1] Although there is a major shift from IV to oral therapy, the price of therapy remains high. A recent study by the American Society of Clinical Oncology found the median monthly patented anticancer drug price to be $8694 in the United States.[2] Third-party payers utilize prior authorizations (PA) to contain costs and ensure that these costly medications are used appropriately. However, the PA process is time consuming and requires a coordinated effort between the patient, provider, and pharmacy. The various parties that are involved in obtaining approval of medications often delay the initiation of a patient's therapy for critical conditions such as cancer.[3]

Studies have explored the correlation between delays and interruption in therapies and the detrimental effects that suboptimal therapy can have on patient outcomes. Ganesan *et al*. studied imatinib compliance and its relationship to clinical outcomes. Nonadherence is shown to adversely affect event free survivals in chronic phase myeloid leukemia (CML). In the study, nonadherence is considered as any dose interruption of more than one week, excluding dose interruptions caused by pregnancy or for toxicity as per physician's recommendation. Of the 516 evaluable patients, 150 patients (29.6% of the cohort) had imatinib dose interruptions of more than one week due to non-adherence. The endpoint measured was the estimated 5-year event free survival (EFS), which was 70.8% for the entire study cohort (95%, CI = 63.3-78.3). The estimated 5-year EFS in patients with nonadherence was 59.8% compared to 76.7% in those with no dose interruptions (P = 0.011).[4]

A delay in the initiation of therapy, specifically due to PA approval, is shown to negatively affect outcomes in other disease states. A study from the Canadian Journal of Cardiology examined the effects of the PA process on the timeliness of clopidogrel prescription filling and clinical consequences, following stent insertion for the prevention of sub-acute stent thrombosis. The study sample comprised 112 patients who received an intracoronary stent and a prescription for clopidogrel upon discharge. Forty-five of these patients had to go through the PA process and suffer a significant delay in filling their clopidogrel prescription putting them at risk of future cardiovascular events. Fewer patients in the PA group than in the non-PA group had their prescription for clopidogrel filled on the day of discharge (31% versus 54%; P=0.02). The median time to fill was 4 days versus 0 days in the PA group and non-PA group, respectively (P=0.04).[5] It is clear that the PA process greatly reduces the likelihood of a patient beginning a drug regimen in a timely manner. This in effect, allows a disease state to remain uncontrolled and perhaps even progress further.

Another study recently published in the *Journal of Managed Care & Specialty Pharmacy* specifically showed the benefits of having a dedicated PA team to shorten the time of authorization and dispensing. The prospective observational study took place over the course of one year and compared PA requests at two clinics, one utilizing the usual care group to conduct the PA and the inter-

vention group utilizing a collaborative practice agreement to streamline the PA process. The time necessary to complete the PA was significantly lower in the intervention clinic than in the usual care clinics (0.53 days vs. 7.02 days, respectively, $P < 0.001$). Additionally, the average PA approval rate was 93% for the intervention clinic and 68% for the usual care clinics ($P=0.0018$).[3]

Having a special task force to expedite the PA process could have numerous benefits for the patient and the healthcare system. A study in the *Journal of Managed Care Pharmacy* analyzed the impact of the PA process for type 2 diabetes medications on overall health care costs. Of the 4,101 members who were retrospectively analyzed, all-cause health care costs (medical and pharmacy) were lowest for the 1,728 individuals in the received authorization cohort. Plan-paid medical costs were $8,192 for the received authorization cohort and $10,127 for the non-qualifying non-filling cohort; this difference in plan-paid medical costs were significant in both the unadjusted and adjusted models ($P=0.005$ and $P<0.001$, respectively).[6] While it may seem that the PA process is time consuming and costly, this analysis shows that the PA process, in terms of cost, is beneficial for the entire healthcare system. When the PA process is utilized and a medication is approved, the overall cost to care for the patient is significantly reduced.

Preliminary studies have already shown that a centralized pharmacist-led PA process can improve both the approval rates and greatly reduce the time to dispense.[2] The PA process in healthcare has become a common step in treating patients. Unfortunately, there is a lack of substantial outcome evaluation of these processes.[7] The few completed studies about the PA process support the need for more controlled studies on the effects of medication coverage on healthcare outcomes.[5]

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Puzzle: Hepatitis C Treatments

By Matthew Kahn, Graphics Editor

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SOLVADI
DAKLINZA
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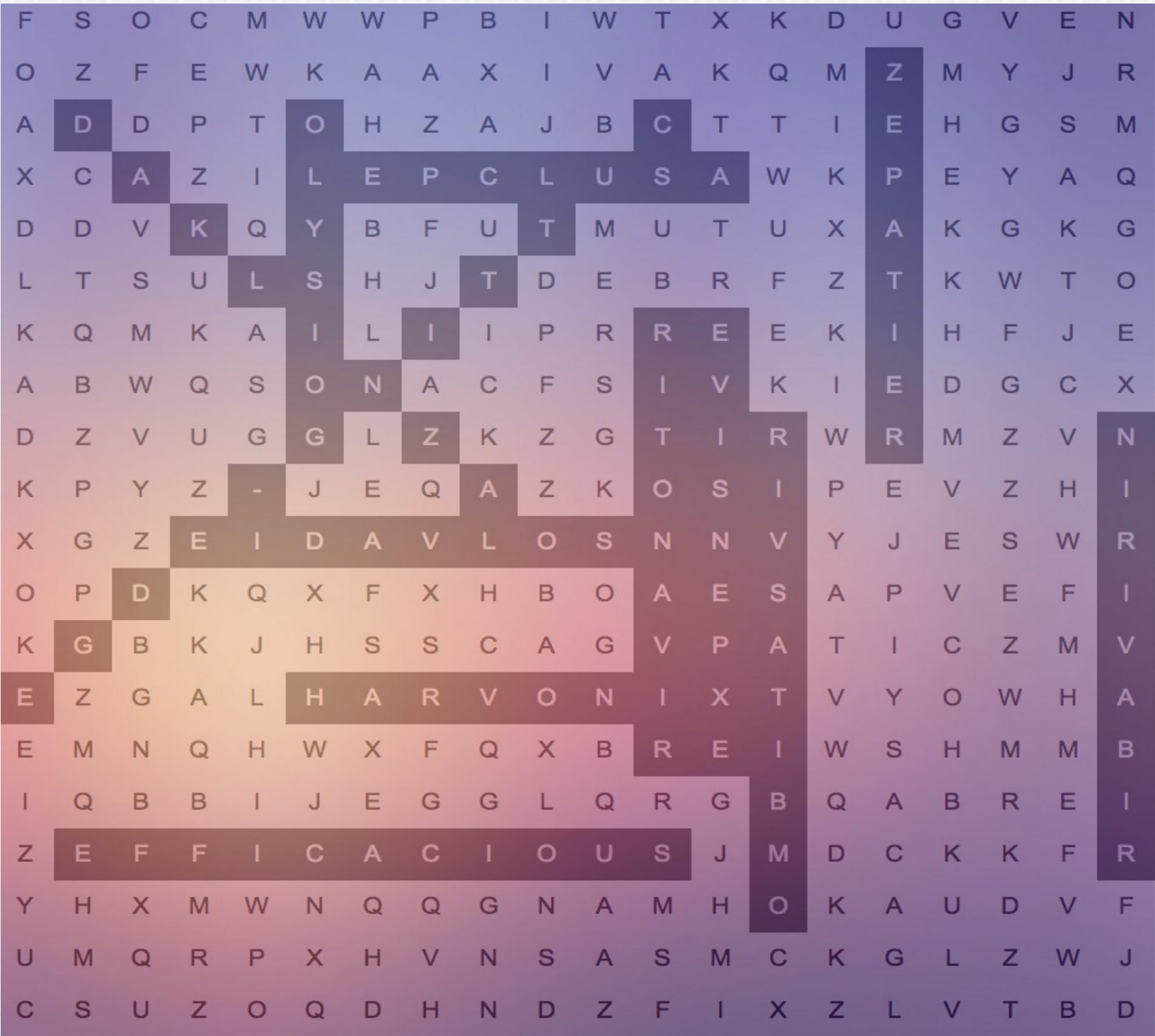
Puzzle: Hepatitis C Treatments

Answers



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RHO CHI POST: TEAM MEMBERS

@ Karen Lin
6th Year, STJ; Editor-in-Chief

The Rho Chi Post allows me to have an appreciation for interactive pharmacy learning as well as the art of writing. With each newsletter, my goal is to provide current information to readers who come across the Post. As an editor, I hope to make the newsletter one-of-a-kind and motivate and influence writers to explore science with their creative talents.

@ Davidta Brown, PharmD
Graduate Copy Editor [Content-Focused]

My two great loves are innovative science and quality writing; 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.

@ Matthew Kahn
5th Year, STJ; Graphics Editor

I've always loved graphic design, so I was thrilled at the opportunity to be a part of the Rho Chi Post team and contribute to future publications. I'm excited to explore new ways to make the Post even better, and also to be continuously exposed to new ideas in the pharmaceutical field.

@ Nicollette Pacheco, PharmD
Graduate Editor [Graphics-Focused]

As a member of the Rho Chi Post team, I have a vast appreciation of what it means to be a pharmacist in the rapidly evolving world of healthcare. As a graduate editor, I will continue to bring my passion for science and creativity to the Rho Chi Post.

@ Sang Hyo Kim
6th Year, STJ; Section Editor: Puzzles

Advances in technology and medicine, as well as improved quality of life, have prolonged lifespans and increased the geriatric population. Pharmaceutical industries and healthcare systems persistently work to find solutions to changing demands and new problems of the society. I wish to learn, educate, and prepare myself and others for the future.

@ Bharat Kirthivasan, PhD
Graduate Copy Editor [Content-Focused]

I received my doctorate 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.

RHO CHI POST: TEAM MEMBERS

@ Jack (Hongkai) Bao

5th Year, STJ; Staff Editor

In my 3rd year of pharmacy school, I was introduced to the Rho Chi Post, an award-winning newsletter run by students. My involvement began by simply reading monthly articles, but as time passed, my passion for writing grew. Coupled with my interest in pharmacy, I made the initiative to apply for a position. Now, as a team member, I believe that the Post is a great way for students and faculty to stay up to date concerning pharmacy news.

@ Anna Diyamandoglu

4th Year, STJ; Staff Writer

Throughout my time in the PharmD program, my understanding of pharmacy as a profession has evolved and deepened as much as my desire to create awareness, particularly to non-science students, about the diverse role pharmacy plays in various healthcare and non-healthcare settings. I have always had an affinity for writing and am looking forward to combining my interests in literary composition and pharmacy to write relevant pieces for Rho Chi Post which both pharmacy students and non-pharmacy students alike will find relatable and take an interest in.

@ Jonathan Mercado

5th Year, STJ; Staff Writer

The Rho Chi Post breaks barriers for students that want a glimpse of their future and acts as an inspiration to work harder to achieve their goals. It is an embodiment of the motivation and intelligence that drives pharmacy students to be the most informed and capable professionals they can be. I am glad to a part of that mission and to channel my passion and interests through this newsletter.

@ Mei Fung

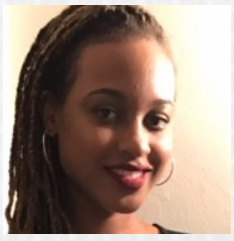
6th Year, STJ; Staff Editor & RCP Website Liaison

It's always interesting to see how the healthcare field evolves and all the advancements in pharmacy come to fruition. I joined the Rho Chi Post because it brings together a variety of these topics with distinguishing perspectives from our peers in pharmacy practice. I am ecstatic to join the team in continuing Rho Chi Post's endeavors in promoting the profession.

@ Anna Chen

4th Year, STJ; Staff Writer

The Rho Chi Post is a fantastic opportunity for future health professionals to keep up with the vastly changing healthcare world. As the pharmaceutical landscape keeps changing, it is crucial that we join the conversation in voicing our opinions and clinical input into current healthcare debates. Healthcare is limitless in possibilities to better patient centered care and I aim to deliver content that is both invigorating and inspiring to both students and practicing professionals.

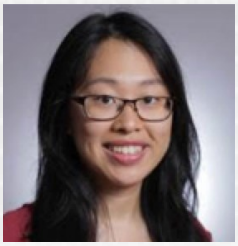


@ Thanesha Graham

5th Year, STJ; Staff Writer

As a writer for the Rho Chi Post, I have the unique opportunity to convey my knowledge, discoveries and interests to the general public. I will be able to enlighten individuals about issues that will not only impact them, but also their families, and communities. I look forward to supplying this newsletter with valuable and relevant information about the evolving field of pharmacy.

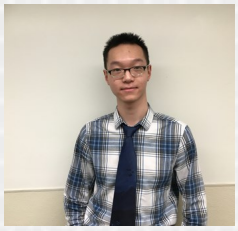
RHO CHI POST: TEAM MEMBERS



@ Vicky Liu

6th Year, STJ; Staff Writer

As a Staff Writer, researching and writing articles about current medicine gives me the opportunity to explore and understand more about pharmacy. I hope that my readers will also feel the same excitement as I do when I learn new things about medicine.



@ Alex Chu

5th Year, STJ; Staff Writer

With a constantly evolving healthcare field, it is imperative that we keep ourselves up to date with the latest news. This is what led me to join the Rho Chi Post, which constantly comes out with interesting and informative topics. It is an honor to write for the Rho Chi Post, and I wish to contribute innovative and intriguing articles to this newsletter.

@ Katharine Russo

3rd Year, STJ; Staff Writer

In my first two years as a pharmacy student, I was exposed to numerous opportunities to write medical based articles for classes and clubs. This is what first sparked my interest in health care literature and I look forward to being a Staff Writer for the Rho Chi Post in hopes of being able to share my passion and enthusiasm in writing health-care related publications.

@ Amy Nguyen

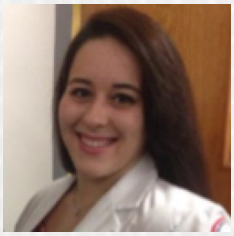
4th Year, STJ; Events and Social Media Manager

Because the pharmaceutical industries and healthcare systems are constantly changing and evolving, it's important to stay up to date on such topics. The student-run Rho Chi Post brings such relevant issues with a creative twist to the table. As the Events and Social Media Manager, I hope to create more outreach events geared towards showcasing the importance and benefits of the Post to students, alumni, and faculty of St. John's University and from other campuses.

@ Angela (Yan Yi) Chan

6th Year, STJ; Staff Writer

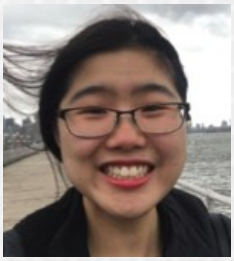
Being part of the Rho Chi Post would help me build experience with writing and reading research articles that would be helpful in my future to stay updated in the innovative world of health. I look forward to being a part of such a great team.



@ Gabrielle Flavoni

6th Year, STJ; Staff Writer

Writing has always been an enormous passion of mine, and I'm blessed to join such an amazing team that encourages me to explore it. As a new Staff Writer for the Post, my goal is to aid others in staying up-to-date about the pharmacy world, while also utilizing a creative outlet to make an impact on those around me.



@ Nicole Cheung

6th Year, STJ; Finance and Outreach Manager

As the Finance and Outreach Manager for the Rho Chi Post, I will act as the primary liaison and collaborate with the Graphics Editor to present information promoting our newsletter to other Rho Chi chapters. Using my experience of applying for NIH and Novo Nordisk Grants, I will assist with writing up proposal budgets as well as maintain accurate financial records. I am proud of our student-operated newsletter publication, and look forward to expanding our organization and network to create more educational workshops and further promote the pharmacy profession.

MISSION

The Rho Chi Post is an award-winning, 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

To provide the highest quality student-operated newsletter with accurate information

To maintain a healthy, respectful, challenging, and rewarding environment for student editors

To cultivate sound relationships with other organizations and individuals who are like-minded and involved in like pursuits

To have a strong, positive impact on fellow students, faculty, and administrators

To contribute ideas and innovations to the Pharmacy profession