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An award-winning, bimonthly, electronic, student-operated newsletter publication by the St. John's University College of Pharmacy and Health Sciences Rho Chi Beta Delta chapter

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

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RHO Rx CHI post

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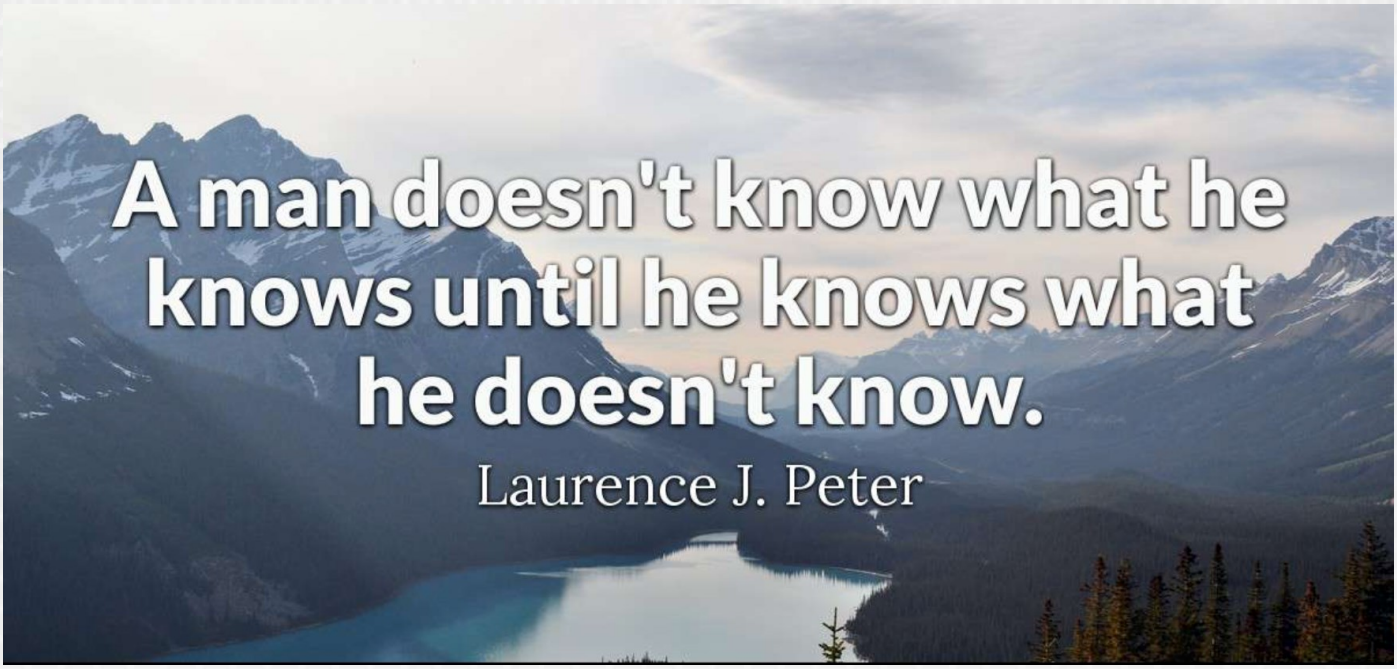
QUOTE OF THE MONTH

By: Matthew Kahn, Graphics Editor



Presentation and management of nivolumab (Opdivo®)-induced pneumonitis

By: Shireen Farzadeh, PharmD Candidate c/o 2019

Nivolumab (Opdivo®) is a monoclonal antibody that blocks programmed death receptor-1 (PD-1). PD-1 plays an important role in the immune checkpoint cascade. It is indicated for the treatment of melanoma, renal cell carcinoma, non-small cell and small cell lung cancer, squamous cell carcinoma of the head and neck, hepatocellular carcinoma, urothelial carcinoma, colorectal cancer, and classical Hodgkin's lymphoma. Nivolumab has been associated with the occurrence pneumonitis, an immune-mediated reaction.[1,2] Signs and symptoms of pneumonitis include cough, chest pain, and shortness of breath.[1] Pneumonitis is identified on computed tomography (CT) imaging with focal or diffuse inflammation of lung tissue.[3] It can occur anytime, but commonly manifests a few months after initiation of treatment.[2] Aside from a CT scan, pneumonitis can be also be identified via chest x-ray or pulse oximetry. Diagnostic work-up, depending on the severity of the pneumonitis, can also include nasal swabs as well as cultures and sensitivities of sputum, blood, and urine samples.[3]

In two studies, the incidence of pneumonitis in patients who received nivolumab was approximately three percent, 1/1994 patients and 4/117 patients, respectively.[1,4] In a case report, a patient presented with fever and cough after three doses of nivolumab.[5] The patient's CT imaging was consistent with aspiration pneumonia. After four days of broad-spectrum antibiotic use, the patient developed ground-glass opacities (GGO). After receiving corticosteroids, the patient's GGO disappeared.[5]

Management of pneumonitis depends on 4 grades of toxicity – G1 (asymptomatic), G2 (symptomatic), G3 (severe symptoms), and G4 (life-threatening). For G1, nivolumab should first be held (not administered). Afterwards, if there is radiographic evidence of improvement or resolution, it may be resumed. If there is no improvement, pneumonitis should be treated as G2, in which nivolumab should be held until it resolves to G1 or less. Prednisone 1 to 2 mg/kg/day can be given with a taper of 5 to 10 mg/week over 4 to 6 weeks. Empirical antibiotics may be prescribed as well. If there is no improvement after 48 to 72 hours of prednisone, the pneumonitis should be treated as G3. In G3 and G4 pneumonitis, nivolumab is recommended to be permanently discontinued. Empiric antibiotics are recommended as well as methylprednisolone IV 1 to 2 mg/kg/day, which should be tapered over 4 to 6 weeks. If the pneumonitis does not improve after 48 hours, infliximab (Remicade®) 5mg/kg, mycophenolate mofetil (CellCept®) IV 1g twice a day, IV immunoglobulin for 5 days, or cyclophosphamide (Cytoxan®) may be added to the regimen.[3]

Pharmacists play an important role on the healthcare team in managing patients with immune-mediated pneumonitis by ensuring that patients are appropriately monitored and managed. Unfortunately, there is no method for patients to prevent immune-mediated pneumonitis.[2,3] However, pharmacists can play a vital role in counseling patients on the tapering directions and the anticipated adverse effects of corticosteroids for treatment of their immune-mediated pneumonitis. They can also help patients who are receiving corticosteroid doses equivalent to or greater than 16 mg of prednisone for 8 weeks. These patients are at a greater risk of developing pneumoncystis pneumonia and pharmacists can recommend prophylactic agents to their doctors. The first-line medication for prophylaxis of pneumocystis pneumonia is oral sulfamethoxazole and trimethoprim (Bactrim®) (See Table 1). Other prophylactic agents include dapsone (Aczone®), dapsone plus pyrimethamine (Daraprim®) and leucovorin (Wellcovorin®), pentamidine

(Pentam®), and atovaquone (Mepron®).[6] Pharmacists can educate patients and healthcare professionals in an interdisciplinary team that despite cases of nivolumab induced pneumonitis, nivolumab has an acceptable long-term safety profile and that the benefits with respect to indicated cancers' survival rates outweigh the risks of acquiring pneumonitis.[7]

Table 1. Drugs for Prophylaxis against Pneumocystis Pneumonia.

Drug	Dose	Route	Comments
Trimethoprim–sulfamethoxazole	1 double-strength tablet daily or 1 single-strength tablet daily	Oral	First choice
	1 double-strength tablet 3 times per week		Alternate choice
Dapsone	50 mg twice daily or 100 mg daily	Oral	Ensure patient does not have glucose-6-phosphate dehydrogenase deficiency
Dapsone plus pyrimethamine plus leucovorin	50 mg daily 50 mg weekly 25 mg weekly	Oral	
Dapsone plus pyrimethamine plus leucovorin	200 mg weekly 75 mg weekly 25 mg weekly	Oral	
Pentamidine	300 mg monthly	Aerosol	
Atovaquone	1500 mg daily	Oral	Give with high-fat meals, for maximal absorption

Thomas CF Jr, Limper AH. N Engl J Med 2004;350:2487-2498.

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Ibalizumab-uiyk (Trogarzo®): a newly FDA approved medication to treat multidrug resistant HIV-1 infection

By: Karen Chen, PharmD Candidate c/o 2019

Ibalizumab-uiyk (Trogarzo®) is specifically indicated for the treatment of human immunodeficiency virus type-1 (HIV-1) infection in combination with other antiretroviral medications in heavily-treatment experienced adults with multidrug resistant HIV-1 infections who are failing their current antiretroviral regimen. Ibalizumab-uiyk is a CD4- directed post-attachment HIV-1 inhibitor that was approved in March 2018 by the FDA.[1] The human immunodeficiency virus is notorious for its ability to genetically mutate at a rapid rate and gain resistance to many of the current antiretroviral therapies on the market. Ibalizumab-uiyk is the first drug in a new class of antiretroviral medications that is approved for multidrug resistant HIV.[2]

Ibalizumab-uiyk is a recombinant humanized monoclonal antibody that works to block HIV-1 virus from infecting CD4+ T cells by binding to domain 2 of CD4+ T cells and interfering with the post-attachment steps required for the entry of the HIV-1 viral particles into host cells.[1,2] Unlike many of the current HIV-1 treatments available, ibalizumab-uiyk is an injection that is administered intravenously as a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every 2 weeks after dilution in 250 mL of 0.9% of Sodium Chloride Injection, USP, by a trained medical professional.[1]

TMB-301 is a single-arm multicenter clinical trial in which 40 subjects, all of whom are heavily treatment-experienced HIV- infected patients, were given ibalizumab-uiyk for 24 weeks. These patients were required to have a viral load greater than 1,000 copies/mL despite being on antiretroviral therapy. Subjects were required to have been treated with antiretrovirals for at least 6 months and be failing or have recently failed therapy to be enrolled in this study. Subjects were also required to have documented resistance to at least one antiretroviral medication from each of the three classes of antiretroviral medications which include nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI) and protease inhibitors (PI), as measured by resistance testing to ensure they had multidrug resistant HIV-1 on a failing HIV treatment regimen.[3] At baseline, 53% of the subjects had been treated with 10 or more antiretroviral drugs prior to trial enrollment. Of that 53% of subjects, 98% percent had been treated with NRTIs, 98% with PIs, 80% with NNRTIs, 78% with integrase strand transfer inhibitors (INSTIs), 30% with glycoprotein- 41 (GP41) fusion inhibitors, and 20% with C-C chemokine receptor type 5 (CCR5) co-receptor antagonists.[1]

Subjects underwent an observational period from Day 0 to Day 6, in which they continued their failing antiretroviral regimen and in which a baseline HIV viral load was established. On Day 7, all subjects continued to receive their failing antiretroviral regimen, in addition to receiving the 2,000 mg loading dose of ibalizumab-uiyk. On Day 14, viral load was assessed for the primary endpoint.[2] The efficacy of ibalizumab-uiyk is measured by the number of HIV-1 viral load copies in the bloodstream from Day 7 to Day 14.[4] On Day 21, subjects were administered the 800 mg maintenance dose of ibalizumab-uiyk every two weeks, concomitant with a susceptible antiretroviral medication, until Week 25. Ibalizumab-uiyk was used to optimize background regimen from Day 14 onward.[2]

Clinical trials have shown that at the end of Day 21, one week after ibalizumab-uiyk was added to subject's current failing antiretroviral treatment, 83% of subjects achieved a $\geq$ 0.5 log10 decrease in viral load.[2] At the end of the clinical trial (Week 25), in which ibalizumab-uiyk was administered in combination with another active

antiretroviral medication, 43% of subjects had a viral load <50 copies/mL and 50% of subjects achieved <200 HIV-1 RNA copies/mL, indicating these subjects had achieved HIV RNA suppression.[2,5] Fifty five percent of subjects had a ≥ 1 log10 reduction in viral load and 48% of subjects had a ≥ 2 log10 reduction in viral load.[2]

It is important to recognize some of the common adverse reactions of ibalizumab-uiyk. Representation of common adverse reactions including diarrhea, dizziness, nausea, and rash occurred in five percent or more of the subjects. One of a few severe side effects that pharmacists should counsel patients on and be aware of is immune reconstitution inflammatory syndrome (IRIS). IRIS occurs during the initial phase of treatment with ibalizumab-uiyk and with other combination antiretroviral therapies where the immune system of an HIV- infected patient may get stronger and begins to fight infections that were hidden. The immune system produces an inflammatory response to indolent or residual opportunistic infections, requiring more complicated treatment.[1]

HIV-1 infected patients who have multi-resistant HIV have limited treatment options. Without an effective and susceptible antiretroviral regimen on board, many of these patients are at risk for HIV- related complications and progression to AIDS. Ibalizumab-uiyk has shown clinical efficacy in those with multidrug resistant HIV-1 infections who are failing their current therapies and can improve outcomes in patients who may have run out of HIV treatment options.

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[Author(s)]. [Article Title]. Rho Chi Post. [Year and Month Published]. [Volume]([Issue]):[Pages].

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Pushing competition and affordability with biosimilars

By: Michael Lim, PharmD Candidate c/o 2020

In an era of widespread pharmaceutical innovation, the rise of biological products is no surprise. Biosimilars – biological products that are highly similar to and have no clinically meaningful differences compared to reference products that are approved by the Food and Drug Administration (FDA) – have taken an increasing role in the treatment of a variety of disease states over the last few years.[1] From cancer to genetic disorders, biosimilars offer a lower-cost alternative and are de facto copies of billion-dollar biotech drugs. Biosimilars are also intended to decrease drug prices through promoting competition in the pharmaceutical market.[2] However, entry of biosimilars to the market is often blocked by court actions.[3] Of the eleven biosimilar drugs that are currently FDA-approved, eight have been kept off the US market via litigation and other strategies employed by big brand-name drug companies such as Amgen or AbbVie.[3] Consequently, despite their cost lowering intentions, prices remain steep with biologics representing almost forty percent of all prescription drug spending and accounting for a seventy percent growth in drug spending from 2010 to 2015.[2,4] The FDA, refusing, "to play regulatory Whac-A-Mole with companies trying to unfairly delay or derail the entry of biosimilar competitors," revealed its Biosimilars Action Plan (BAP) in July 2018.[3]

The BAP emphasizes four main strategies supported by a plethora of key actions. These strategies include improving the efficiency of the biosimilar development and approval process, clarifying regulatory information, improving communication and understanding of biosimilars, and fostering competition.[5] Building on the 2010 Biologics Price Competition and Innovation Act, the plan includes key actions to facilitate the approval and entry of biosimilars to the market. For example, to accelerate the biosimilar approval process, the plan revealed a goal of creating biosimilar-review templates.[3] These standardized review templates aim to improve the efficiency of FDA review and increase public information about the FDA's product evaluation.[2] In addition, the plan mentions the creation of development tools to assist biosimilar drug development.[2] These tools include silico models and simulations to help correlate pharmacokinetic and pharmacodynamic responses of drugs with their actual clinical performance.[2] The BAP also calls for the development of an index of critical quality attributes which would be used to compare potential biosimilars to reference products.[2]

To improve coordination with regard to development and approval activities, the FDA plans to transition its current biological product management staff to establish an Office of Therapeutic Biologics and Biosimilars (OTBB).[2] With this new central hub, the FDA expects to accelerate response time to stakeholders, provide advice to developers, review application materials, and create guidance documents to support policy development and supply regulatory clarification of the biosimilar approval process.[2] While these actions enhance coordination at the national level, the BAP also outlines outreach beyond the United States. By strengthening partnerships with regulatory authorities in Europe, Japan, and Canada, the FDA anticipates even greater coordination and efficiency in developing biosimilars.[2]

In hope of being able to furnish easy and applicable information about biological products, enhancements to the Purple Book, which lists all FDA-approved biologic and biosimilar products, are scheduled.[2] Additionally, advanced efforts are planned for data collection and spreading education on the topic of biosimilars.[2] Some methods to be utilized in the future include educational videos that explain key concepts about biosimilars and webinars that emphasize the rigor of the development and approval process.[2] Through these lessons, the BAP forecasts improved understanding among patients, clinicians, and payers.[2]

To promote competition, the action plan calls for the evaluation of firms that may be manipulating regulatory requirements to unfairly delay the introduction of new biosimilars to the market.[2] For instance, some drug makers will refuse to sell drug samples that are necessary for developing the generic or biosimilar product.[2] As a result, entry of these potential biosimilars to the market is prevented. Coordinating with both the Federal Trade Commission and legislators, the FDA will combat such anticompetitive behavior and seal any regulatory loopholes that are being exploited to create delays.[2]

The FDA serves an important role in balancing innovation with competition. While incentives such as exclusivity periods entice developers to pioneer new biological products, competition which lowers prices must also become available when such periods have lapsed. In fact, an analysis has shown that if Americans had the opportunity to purchase more successfully marketed biosimilars, they would have collectively saved more than $4.5 billion in 2017.[5] With the FDA's Biosimilar Action Plan, a fairer and more streamlined approach to introducing new biosimilars to the market may be on the horizon.

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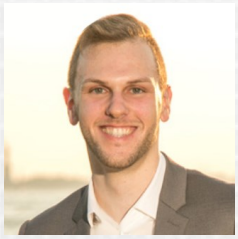
RHO CHI POST: TEAM MEMBERS

@ Anna Diyamandoglu

5th Year, STJ; Editor-in-Chief

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 look forward to combining my interests in literary composition, editing and pharmacy to produce relevant issues which both pharmacy students and non-pharmacy students alike will find relatable and take an interest in.



@ Matthew Kahn

6th 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.

@ Mei Fung

Graduate Copy Editor [Content-Focused]

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.

@ Karen Lin

Graduate Copy Editor [Content-Focused]

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.

@ 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.

@ Davidta Brown, PharmD

Graduate Copy Editor [Content-Focused]

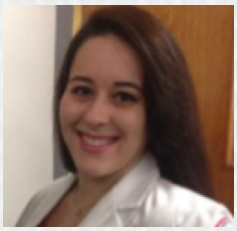
My two great loves are innovative science and quality writing; the Rho Chi Post is an insightful combination of both. As an editor, I look forward to bringing relevant information and fresh perspectives to the student and faculty of St. John's University, as well as to making the Rho Chi Post a newsletter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

RHO CHI POST: TEAM MEMBERS

@ Jonathan Mercado

6th Year, STJ; Finance and Outreach Manager, 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.



@ Gabrielle Flavoni

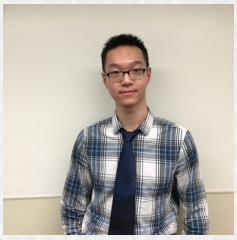
Graduate Staff Editor

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.

@ Kathleen Horan

5th Year, STJ; Staff Editor

I have always loved writing, and I hope to couple my passion for writing with my interest in clinical pharmacy by becoming a writer and staff editor for the Rho Chi Post. As a writer and staff editor for the Rho Chi Post, I hope to write and edit informative and interesting articles that relate to the world of healthcare and pharmacy. I am so excited to join this team of student pharmacists and writers.



@ Alex Chu

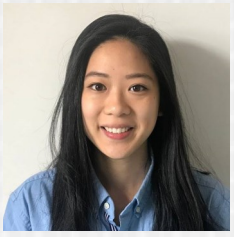
6th Year, STJ; Staff Writer

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.

@ *Anna Chen*

5th 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.



@ Karen Chen

6th Year, STJ; Staff Writer

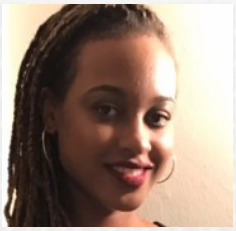
I am honored to be writing for the Rho Chi Post. The Rho Chi Post allows me to creatively express my opinions on various topics in pharmacy as well as communicate and share new information about our ever evolving profession. This platform connects students, allows us to educate each other and helps us all stay up to date. I have always loved writing and hope that by being a part of the Rho Chi Post team, I can continue to research and write articles that

RHO CHI POST: TEAM MEMBERS

@ Joseph Eskandrous

6th Year, STJ; Staff Writer

In the world of pharmacy, knowledge becomes outdated within hours of when you learned it. The miracle drug that used to be considered the standard of therapy is replaced by the latest and greatest. My role as a Staff Writer for the Rho Chi Post is to bring these changes to the forefront in order to empower future pharmacists and to improve the quality of patient care.



@ Thanesha Graham

6th 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.

@ Michael Lim

5th Year, STJ; Staff Writer

In the spirit of advancing the pharmacy profession, the Rho Chi Post never ceases to produce valuable content showcasing the innovation and diversity of the career. As a Staff Writer for the Post, I am honored to have the opportunity to use writing to both educate and push readers to strive for excellence in their professional pursuits. I hope that my contributions to the newsletter are able to foster growth in an informative and accessible manner.

@ Shivani Shah

4th Year, STJ; Staff Writer

As students in an dynamic healthcare profession, it is important to keep up to date with literature and publications regarding the pharmacy profession. Rho Chi Post serves as a great outlet for students to catch up on pharmaceutical innovations and progress going on in the career. Being a staff writer motivates me to constantly research and share new, exciting advancements with fellow students. I look forward to reading articles in the Post and hope to spark others curiosity and interest!

@ Shireen Farzadeh

6th Year, STJ; Staff Writer

I am excited to join Rho Chi Post and contribute to the award-winning newsletter for students to share ideas, opinions, and pertinent topics! Writing for the Rho Chi Post is an opportunity to express our appreciation for pharmacy and educate ourselves and our peers. I hope to inspire students to discover their passion for writing and to stay up to date on our evolving profession!

@ Yao Jiang

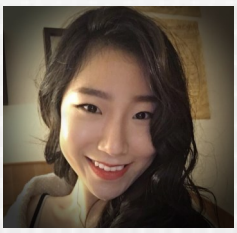
6th Year, STJ; Staff Writer

Writing for the Rho Chi Post allows me to bridge the gap between class and the real world. It gives me a reason to focus on topics that are relevant to me as a practicing student pharmacist and explore new medications, laws, and ventures in our evolving profession. This process of researching, teaching oneself, and finally, teaching others is what we will ultimately do as future pharmacists. I am honored for this opportunity to be further exposed to what pharmacy has to offer all while giving back to the community that has taught me so much.

@ Katharine Russo

4th 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.



@ Yeonah Suk

5th Year, STJ; Staff Writer

As a student interested in various branches of healthcare, the Rho Chi Post has provided me the opportunity to be part of an organization that discusses this field in a broad scope. As modern society continues to amalgamate and globalize multiple disciplines, it is important that we harmonize these elements and keep ourselves updated on their interactions. I joined the Rho Chi Post to both learn and contribute to a team that has immense diversity and my goal is to continue exploring innovative ideas through writing.

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