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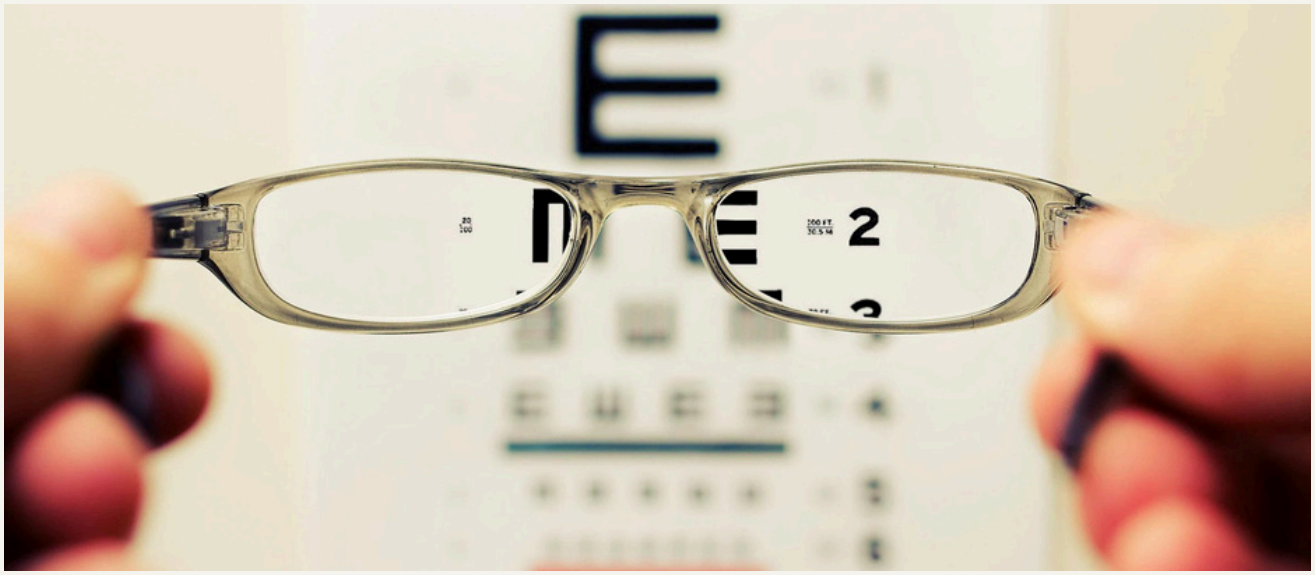
RHO PxCHI post

St. John's University College of Pharmacy & Health Sciences



THIS ISSUE'S FEATURED ARTICLE:

FROM WEIGHT LOSS TO VISION LOSS: A POTENTIAL RISK OF SEMAGLUTIDE

About the Rho Chi Post

The Rho Chi Post was developed by the St. John's University Rho Chi Beta Delta Chapter in October 2011 as an electronic, student-operated newsletter publication with a team of three student editors and one Editor-in-Chief. Today, our newsletter boasts 12 volumes, over 90 published issues, and more than 600 unique articles to date with an editorial team of first to sixth year student pharmacists, as well as returning PharmD graduates.

The newsletter is distributed by St. John's University College of Pharmacy and Health Sciences to more than 1,500 students and faculty members. Our monthly electronic mailing list continues to extend readership far beyond campus.

Mission

The Rho Chi Post is an award-winning, 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 and faculty.

Vision

The Rho Chi Post aims to become the most creative and informative 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 sets the stage for the development of individual writing skills, collaborative team work, and leadership.

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FROM THE EDITOR

A Message from the Editor-in-Chief, Anjali Thykattil

It is with great honor that I introduce the Rho Chi Post's final issue of our 13th volume. I thank you for taking time out of your day to read over our newsletter. It is my intention that this issue teaches you something new, whether it be clinical, pharmacy news, or advice from our Rho Chi Talks or 6th Year Perspective. I would like to take a moment to thank our Editorial Team, Executive Board, advisors, and readers as this newsletter would not be possible without them. With this, I leave you to the rest of the issue, and good luck to all this upcoming academic year!

Frequently Asked Questions

Who can write for the Rho Chi Post Newsletter?

Anyone can write for the Rho Chi Post! Our newsletter is not exclusive to St. John's University students. The Rho Chi Post accepts articles on a daily basis!

How do I submit an article?

You can submit an article by creating an account on our website! Go to www.rhochistj.org/RhoChiPost, click the login button from the upper menu bar, and click register. Upon making an account, you will be able to submit articles to our author inbox.

Who determines article topics?

You are free to choose an article topic of your choice. Take a look at our Author Guidelines for ideas.

What happens after I upload my draft article on the Rho Chi Post website?

Our Editor-In-Chief (EIC) will either edit the article directly or assign the article to a staff editor. If any revisions are needed, the editor will upload the article back to the portal, notifying the author via email. The author can then download the edited article, make the suggested revisions, and reupload the draft back to the portal. Additional drafts will be revaluated by our copy editors and then EIC, repeating this process. Once no further revisions are needed, the article is accepted for publication.

Is there a deadline for authors to send revisions?

There is no deadline to submit revisions for an article. However, the quicker revisions are made, the quicker the article can move through our editing process. Once an article is accepted for publication, it will be moved into a queue to be placed into an upcoming issue.

FDA's New Blueprint for Cell-Based Therapies

By: Reyaz Mussaleen PharmD Candidate c/o 2027

Introduction

The Food and Drug Administration (FDA) of the United States published a draft guidance in April 2024 titled "Safety Testing of Human Allogeneic Cells Expanded for Use in Cell-Based Medical Products."[1] This document, which aims to improve the regulatory framework for cell-based therapies, demonstrates the FDA's determination to modify its regulatory oversight in order to keep up with the swift advances in biotechnology and medicine. It focuses on offering allogeneic cell therapy safety assessment methodologies and stresses a risk-based strategy adapted to the complexity of contemporary biologics.

Enhancing Regulatory Framework

This guidance aims to improve current FDA papers by clarifying the safety testing requirements for Biologics License Applications (BLA) and Investigational New Drug Applications (IND), thereby offering an organized process[2] for the approval of cell-based products. It discusses how different medical products including live cells, inactivated cells, and cell lysates are made using allogeneic cells, including genetically modified ones. This program is a component of the FDA's larger endeavor to guarantee patient safety and promote creativity in the creation of novel treatments.

Public Engagement and Feedback

Given the significance of stakeholder feedback, the FDA has extended the[3] public comment period for the draft until July 29, 2024. The public and developers may offer input at this time that will be very helpful in improving the guidelines. To ensure extensive community involvement in the finalization of the guidelines, stakeholders are encouraged to submit comments electronically via the Federal eRulemaking Portal or by regular mail.

Educational Initiatives and Industry Collaboration

The FDA has initiated the Cellular and Gene Therapies Interactive Site Tours Program in conjunction with[4] the publication of the revised safety guidelines. Through visits to manufacturing facilities and workshops, this effort aims to improve FDA staff members' comprehension of the manufacturing process for cell and gene therapy products. The objective of this program is to close the knowledge gap between industry standards and regulatory requirements. Thus, improving the effectiveness of the regulatory review process by giving FDA staff members direct access to the operational difficulties and advancements in therapeutic production.

Risk-Based Approach to Safety Testing

A risk-based safety testing approach that accounts for the possible patient population, the reagents employed in the cells' growth, and the cells' capacity for expansion[5] is at the heart of the FDA's proposed guidance. This method guarantees that safety procedures are both thorough and specially designed to address the risks connected to various cell-based products. The guidelines also specify the regulatory

requirements for cells with restricted expansion capacities as well as continuous and highly expandable cells.

Implications for the Future

The proactive strategy taken by the FDA, which includes the instructional site tours and updated safety rules, points to a major move in the direction of more dynamic and knowledgeable regulatory methods. Through the integration of comprehensive safety rules with direct industry contact, the FDA is establishing a global standard for regulatory bodies. By bringing regulatory requirements up to date with the most recent scientific discoveries, this approach not only promotes the industry's expansion but also improves the safety and effectiveness of cell-based therapies.

Conclusion

The FDA is taking a progressive approach to regulating the complicated field of cell and gene treatments, as seen by its most recent initiatives, which include the publishing of the draft guidance and the interactive site visits program. The goal of these initiatives is to guarantee that, as the biotech sector develops, it will continue to adhere to safety regulations that safeguard public health and promote scientific advancement. The thorough guidelines and teaching program have the potential to improve the processes involved in the development and approval of novel medicines, which will in turn speed up their availability to patients who most need them. This dual emphasis on improving education and adhering to regulations precisely is going to change the way biologic product development and approval are done.

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Rho Chi Talks: A Look into the St. John's University Summer Research Program

Featuring: Sei Higuchi, Ph.D.
By: Rosa Kang PharmD Candidate c/o 2027

Summer is a time of endless possibilities. During this time, St. John's University offers a program for its students who are interested in pursuing research: The Summer Research Program! Here are just a few of the many experiences from the professors and students who are participating in this year's program and their takeaways.

Tell me about yourself!

I was born and raised in Japan. I did my 4-year post-doctoral track in Kyoto University and then, in 2015, moved to New York to work with Columbia University. In 2022, I began working and teaching at St. John's University. My field of study is molecular biology, specifically regarding obesity and diabetes. I have a keen interest in reptiles, most favourably, snakes. In fact, the research that I do now is based on how snake bile acid works and how it may help with human obesity/diabetes issues.

What are some qualities you looked for when selecting students for the program?

I believe in working with driven students. It is hard to know a student purely based on their application, but ultimately it comes down to how interested you are in research (and the type of research as well). Students who have specific career paths and generally know what they would like to do in the future are always a pleasure to work with. Also, punctuality and valuing peoples' time is always a plus!

How did you get started in being a summer Research Mentor?

I am always happy to work with motivated students. I know from personal experience how hard doing research is by yourself, so by being a Summer Research Mentor, I get to work with these passionate students and guide them in their research journey. At the same time, I get the added bonus of having an extra hand in the lab! It's a fun and efficient way to complete lab work and ultimately, everyone learns from each other.

What is your lab research about?

My research primarily focuses on diabetes and obesity, specifically on how to best treat it. I am very intrigued by the intestines. So, one of the topics I study is how our intestines affect our brains. Glucose metabolism, which occurs in the gut, directly affects neurotransmitters. To further study this, I use optogenetics to see how gut activity can activate brain activity. Currently, it's a field that has little research, so I'm excited to explore further!

Another research project that I am working on is figuring out how snake bile acid works and seeing if we can implement its use in diabetes/obesity treatment. When my son got a pet snake, snake would be dormant for days and weeks. I was worried it would die. Despite not eating for long periods of time, the snake maintained a healthy body weight and had normal bodily functions. This made me curious as to what sustains the snake for so long. Later, I discovered that snake bile acid affects mitochondria functions to maintain the body without having to ingest nutrients. So, using luciferase assay to see how well bile acid and the respective receptor binds together, I am able to observe how well bile acid affects mitochondrial functions. These are just a few things I've been doing in my lab.

What is the most rewarding part of this program?

Seeing what and how much each student can bring to the table is always a pleasant surprise. I worked with a high school student last year who had so much talent and drive. She's recently received awards for the work she did in the lab. Being able to help and give students the right tools to achieve their full potential is always the most rewarding part about mentoring.

Any advice for students who may apply for the program in the future?

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At the end of the day, anyone who is interested in research deserves to have the opportunity to let their passion flourish. Do not hesitate to reach out to any professors that does research that interests you. Just by showing your genuine interest, you're sure to get a spot!

Students

Tell me a little bit about yourself!

Gabriella Coletta: Hi, I'm a Junior Biomed Science major. I am in 3 organisations on campus: the Cooking Club, Phi Sigma, and Women in Stem. I've also started on the softball team and am a Medical Assistant in the paediatrics field.

Kareena Poonai: My name is Kareena, and I'm a junior majoring in biology. I am involved on campus through Project Sunshine and Student Wellness Government. I also work as a Medical Assistant and as a Speech and Debate Coach. I enjoy musical theatre on the side!

What made you want to pursue research?

Gabriella Coletta: I think the fact that medicine is an everchanging field is fascinating. You never know what's around the corner, so this is a great opportunity to be a part of the journey to innovation. Also, research teaches you so much that you just can't learn in a lecture hall. It's a very tangible learning experience, which I've always wanted.

Kareena Poonai: I enjoy the hands-on experience and learning environment. I've also always been invested in anxiety and depression research, and seeing what science can do to help with people struggling with these disorders. I wanted to experience as much hands on experience as I can on the field to truly make an impact down the line.

Why did you choose this lab specifically, or what made it your final choice?

Gabriella Coletta: I was in Dr. Higuchi's anatomy course last semester and when he brought up his lab research from time to time, I was immediately intrigued so I reached out to him and the rest is history!

Kareena Poonai: I heard about Dr. Higuchi's lab when I was taking his anatomy class. I was very interested in the work he does with bile acid and the linkage between gut activity and mental disorders, so I reached out to him regarding a potential shadowing opportunity, and later to be a research assistant.

What research projects are you working on this year?

Gabriella Coletta: Last semester, we identified 28 python-specific P45 cytochrome gene and from gene information, we designed specific primer for qPCR. Seven of 28 genes were detectable and are candidate of enzyme for pythocholic acid synthesis because of high expression in the python liver. After performing DNA digestion and inserting these genes into plasmids, we will insert these plasmids into cells. This will allow us to identify if the plasmids are effective and good candidates for future use. The goal of the summer research program is to continue the work I was previously performing in the lab, practice inserting plasmids into cells, and, eventually, insert the plasmids we made with genes we identified into cells.

Kareena Poonai: I am working on the behavioural aspect of mice which includes depression and anxiety. Anxiety and depression are the most prevalent mental disorders. The study is aimed to investigate the relationship between anxiety, depression and microbiota using TGR5 knockout mice. Imbalances in bile acid metabolism and changes in the composition of the gut microbiota have been linked to depression and anxiety. Responsibilities in lab include lab maintenance, documentation, and conducting this new experiment.

How did you find out about the program?

Gabriella Coletta: Dr. Higuchi talked about his lab and research in class and that piqued my interest. I was already enjoying his classes so when he brought up his research, I was highly motivated to reach out to him about shadowing his lab. I did lab shadowing for a semester, then I got an email from the school about summer research opportunities, which led me to officially apply for his lab as a research assistant.

Kareena Poonai: Like Gabriella, I was shadowing Dr. Higuchi's lab during the semester, then I got an email from the school regarding the Summer Research Program, so I naturally applied for Dr. Higuchi's lab.

What is the most rewarding part about being in this program so far?

Gabriella Coletta: I'm learning so much in a laboratory that I don't truly get to in class. The hands-on approach really allows me to apply my knowledge and hone new skills. Also, being able to handle instruments and chemicals that I usually don't get to is always exciting.

Kareena Poonai: Being able to actually apply my knowledge in an engaging learning environment is so rewarding.

Specifically with the work I am doing right now it's so much fun observing the behavioural aspect of the mice and how they react to each trial.

Any advice for your peers who are considering applying or tips in general when getting started in research?

Gabriella Coletta: Don't be intimidated; don't hesitate to out to professors or faculty that you would like to work with. Even if you might not feel as qualified, this is part of the process of learning so professors will be more than happy to help you along the way, so if research is your thing go for it!

Kareena Poonai: Ask your professors about anything and everything! It's a great way to learn more about the field and figure out what you would want to do. At the end of the day, professors are more than happy to discuss with you their research projects and if you are interested in learning more about it, they will be more than happy to help you get there.

FDA Accelerated Approval of Enhertu for Broad Treatment of HER2-Positive Solid Cancers

By: Nivaj Haque PharmD Candidate c/o 2027

In recent years, advancements in oncology have transformed the treatment landscape for various cancers, including those overexpressing human epidermal growth factor receptor 2 (HER2). Approximately 15-20% of breast cancers and a significant proportion of gastric and lung cancers are HER2-positive, making this a critical target for innovative therapies.[1] These cancers tend to be more aggressive and have poorer prognosis compared to HER2-negative cancers, necessitating the development of more effective treatments.[2]

Recommendations for the treatment of HER2-positive cancers are established by prominent organizations such as the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN). These organizations recommend a combination of targeted therapies and chemotherapy as first-line treatment for HER2-positive cancers. In addition to traditional chemotherapy, targeted therapies like trastuzumab (Herceptin) and pertuzumab (Perjeta) have been instrumental[3,4] in improving outcomes for patients. These guidelines emphasize the importance of personalized treatment plans based on the individual characteristics of each patient's cancer

HER2-positive cancers result from the overexpression of the HER2 protein, which promotes the growth and spread of cancer cells. This overexpression is linked to a higher likelihood of recurrence and resistance to conventional therapies.[5] The introduction of targeted treatments has provided new hope for patients, significantly improving survival rates and quality of life.

One of the most promising therapies in this area is fam-trastuzumab deruxtecan-nxki (Enhertu), a HER2-directed antibody and topoisomerase inhibitor conjugate, developed by Daiichi Sankyo and AstraZeneca. Enhertu received accelerated approval from the FDA for the treatment of HER2-positive breast cancer in December 2019, and its indications have since expanded. On January 15, 2024, the FDA granted accelerated approval for Enhertu to treat any HER2-positive solid tumor that has progressed following prior treatment or for which there are no satisfactory alternative[6] treatment options.

Enhertu's mechanism of action involves binding to the HER2 receptor on cancer cells, delivering a cytotoxic payload directly into the cell, thereby inducing cell death. This targeted approach helps to minimize damage to healthy cells, making it a potent and precise[7] treatment option. Enhertu is administered via intravenous infusion. The recommended dose is 5.4 mg/kg every three weeks until disease progression or unacceptable toxicity. Common side effects include nausea, fatigue, vomiting, alopecia, constipation, and neutropenia. Serious adverse reactions, such as interstitial

lung disease and pneumonitis[6], require careful monitoring and management.

Clinical trials have demonstrated the efficacy of Enhertu across various HER2-positive cancers. The DESTINY-PanTumor02 trial, a significant multicenter, open-label, single-arm study, evaluated the efficacy and safety of Enhertu in patients with advanced HER2-positive solid tumors. This trial enrolled 276 patients with various HER2-expressing tumors, including breast, gastric, colorectal, and non-small cell lung cancers, among others. The primary endpoint was the objective response rate (ORR), with secondary endpoints including duration of response (DoR), progression-free survival (PFS)[8], and overall survival (OS).

Key findings from the trial included an investigator-assessed ORR of 37% in a heavily pretreated patient population, with a median DoR of 11.8 months. Additionally, the study highlighted that patients with higher HER2 expression (IHC 3+) had an even higher ORR of around 61%, with a DoR of 22.1 months. The ORR across all tumor types was 45.3%, with a median DoR of 11.3 months. The median PFS[8] was 8.2 months, and the median OS was 14.7 months. These results highlight Enhertu's potential to provide meaningful clinical benefits to patients with HER2-positive solid tumors, regardless of the tumor's origin.

The accelerated approval of Enhertu for the treatment of HER2-positive solid tumors marks a significant advancement in oncology. It provides a new treatment option for patients with difficult-to-treat cancers, offering hope for improved outcomes. Continued studies and real-world evidence will further define Enhertu's role in the treatment landscape and may lead to full approval based on confirmatory trial results.

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From Weight Loss to Vision Loss: A Potential Risk of Semaglutide

By: Sariah Grant, PharmD Candidate c/o 2027

In June of 2021, the Food and Drug Administration (FDA) approved Novo Nordic's semaglutide, marketed under the brand name Wegovy. It was approved for adults facing obesity and other weight-related conditions.[1] Initially developed for the management of type 2 diabetes mellitus (T2D), semaglutide's use has expanded significantly due to its efficacy in promoting weight loss. Wegovy and other semaglutide brand names, including Ozempic and Rybelsus, have quickly become staples in weight-loss therapy.[2]

Several factors have contributed to semaglutide's success, including its effectiveness in treating diabetes and, more recently, its efficacy in reducing body weight.[2] According to the Centers for Disease Control and Prevention (CDC), over 70% of Americans face obesity or issues with being overweight.[3] It is an issue that can no longer be treated lightly. Given the associated health risks, intervention is needed as a preventative measure. The FDA recognizes obesity as a serious health crisis linked to major health issues including heart disease, stroke, diabetes, and an increased risk of certain types of cancer.

Despite the clinical benefits of semaglutide, researchers at Harvard Medical School have identified a potential risk associated with the drug's use, specifically linking it to the development of non-arteritic anterior ischemic optic neuropathy[4] (NAION). This eye disease is characterized by vision loss, which may influence decisions regarding the prescription and use of semaglutide.[5]

Semaglutide Mechanism and Uses

Semaglutide mimics an incretin hormone, which causes a decrease in blood sugar levels. This hormone is produced in the intestines after specific nutrients enter the pathway and neural impulses indicate food intake. Semaglutide is classified as a glucagon-like peptide 1 receptor (GLP-1) agonist.[6] GLP-1 agonists work by stimulating the release and secretion of insulin from the pancreatic islets when glucose levels are elevated, usually after eating. It also suppresses the release of glucagon, which raises blood sugar levels.

Additionally, semaglutide decreases appetite, promotes satiety, and decreases how much one desires to eat.[6]

The Semaglutide Treatment Effect in People with Obesity (STEP) program was a series of randomized phase 3 clinical trials aimed to evaluate the safety and efficacy of the 2.4 mg dose of semaglutide used for weight-loss.6 The STEP program revealed that only 7.6% of participants did not see greater than a 5% average weight loss after taking subcutaneous semaglutide for 12 weeks. These results indicate that semaglutide has a high average weight loss efficacy.[6]

Understanding NAION

Non-arteritic anterior ischemic optic neuropathy (NAION) is an ophthalmic condition characterized by acute vision lossand is the second most common type of optic neuropathy in adults.[4,5] It occurs due to impaired blood flow, resulting in ischemia and subsequent damage to the optic nerve[7] head. The exact etiology of this ischemia is unclear. However, a well-accepted proposed risk factor is a congenitally small optic nerve head structure. This anatomical variation increases the likelihood of crowding of axons within the protective layer of the optic nerve, known as the dural sheath. Such crowding may cause vascular compression and edema, ultimately leading to ischemia. Other believed risk factors include obstructive sleep apnea, nocturnal systemic hypotension, hypertension, being over 50,[7] hypercholesterolemia, diabetes mellitus, and the use of certain medications.

Clinical manifestations of NAION are characterized by acute, painless, unilateral[5] vision loss, usually noticed upon waking. This vision loss may include altitudinal vision loss, and/or color-blindness.

Upon eye examination, the patient's optic disc appears swollen due to edema. Currently, there is no effective therapy for NAION. Several treatments have been attempted, but most have been inadequately studied.[5]

The Risk of NAION for Patients on Semaglutide

A retrospective cohort study was conducted by Boston researchers at Harvard Medical School to determine if semaglutide treatment is associated with an increased risk of nonarteritic anterior ischemic optic neuropathy (NAION). The study collected data on patients with NAION diagnoses from a centralized registry at Harvard's Massachusetts Eye and Ear teaching hospital. Researchers collected data on variables such as age, sex, race, diseases, and conditions, mainly focusing on type 2 diabetes and overweight or obesity statuses. The data spanned from December 1, 2017, to November 30, 2023, covering the period of semaglutide's approval for type 2 diabetes and weight loss, as well as tracking patient outcomes. Any occurrence of NAION reported prior to the start date was excluded, as were any patients younger than 12 years of age, per FDA age requirements for semaglutide. Researchers designed a propensity score-matched cohort study to compare patients who took semaglutide with those who took non-GLP-1 receptor agonist drugs for type 2 diabetes and weight loss. The cohorts were matched based on similar covarying factors including sex, age, obesity, obstructive sleep apnea, systemic hypertension, type 2 diabetes,[4] hyperlipidemia, etc.

Researchers tracked cumulative incidences of NAION using the Kaplan-Meier survival analysis, and the Cox proportional hazards

egression model. The Kaplan-Meier survival analysis measures the fraction of living patients for a period after treatment.8 The study spanned from the time of the first prescription of semaglutide or non-GLP-1 treatment until the first event of NAION, death, or the end of the 36-month period.[4] The Cox proportional hazard regression model, calculates the hazard ratio of an endpoint associated with a specific risk factor and the probability of the event to occur.[9]

The type 2 diabetes study included 710 patients. Among these, 17 patients on semaglutide were diagnosed with NAION, compared to only 6 in the non-GLP-1 treatment cohort. The Kaplan-Meier survival analysis determined a cumulative incidence of 8.9% (95% CI, 4.5%-13.1%) for the semaglutide group, compared to only 1.8% (95% CI, 0%-3.5%) for the non-semaglutide group after 36 months. The Cox proportional hazards regression model yielded a high hazard ratio of 4.28 (95% CI, 1.62-11.29) (P<.001), indicating a higher risk of NAION in the semaglutide cohort compared to the non-GLP-1 treatment cohort.[4]

The overweight or obesity study included 979 patients. Of these, 20 patients in the semaglutide treatment cohort developed NAION, compared to only 3 in the non-GLP-1 treatment cohort. At 36 months, the Kaplan-Meier survival analysis calculated a cumulative incidence of NAION of 6.7% (95% CI, 3.6%-9.7%) for the semaglutide treatment cohort, versus 0.8% (95% CI, 0%-1.8%) for the non-GLP-1 treatment cohort. Additionally, the Cox proportional hazard regression model resulted in a high hazard ratio of 7.64 (95% CI, 2.21-26.36) (P<.001), indicating a higher risk of NAION in the semaglutide cohort compared to the non-GLP-1 treatment group.[4]

Discussion

The findings of both studies have led researchers to two key conclusions. First, patients taking semaglutide are at an increased risk of developing NAION. Second, there appears to be a higher chance of developing NAION among the overweight and obese cohort compared to the type 2 diabetes cohort. Although the results of the study seem conclusive, the researchers at Harvard Medical School acknowledge several limitations in their research. These limitations include that data was collected from an institution which specializes in ophthalmology, and thus may not be reflective of the generalized use of semaglutide. The study also does not factor any biases of semaglutide prescription to patients, does not confirm patient's adherence to treatment, and is limited to data within the institution. Crucially, this data could not be conclusive as it does not assess risk reduction after discontinuing a medication or evaluate dose-dependent risk factors as required by the FDA.[4]

Conclusion

Given the limitations in this study, further research is necessary to align with FDA risk assessment procedures. Until a more definitive study is conducted, it is recommended that patients should continue their medications as prescribed[4] and consult with their healthcare providers regarding any concerns. However, if a future study confirms that there is an association between semaglutide and non-artertic anterior ischemic optic neuropathy, healthcare providers may need to reassess the prescribing of Ozempic, Rybelsus, and Wegovy, weighing both the potential risks and benefits.

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Cystic Fibrosis Therapy Diminishes Hyper-Inflammation In COVID-19-Related Pneumonia

By: Michelle Flores, Pharm D Candidate c/o 2027

According to clinical trial results from researchers at UCL, UCLH, and the Francis Crick Institute in the UK, dornase alfa, a drug commonly used to treat cystic fibrosis, improved outcomes for patients with severe COVID-19 pneumonia and may be used to treat other respiratory infections. A randomized unblinded trial sought to determine whether nebulized dornase alfa could mitigate the severe inflammation often seen in COVID-19 pneumonia and improve[1] patient outcomes.

The study, published in the scientific journal, eLife, found that the drug, “Dornase alfa” reduced hyper-inflammation in COVID-19 pneumonia patients. Hyper-inflammation occurs when the body's immune system reacts too strongly and may lead to tissue damage and death. Dornase alfa can potentially treat a range of respiratory infections, including those caused by influenza or bacterial pneumonia. It may also be beneficial for managing lung diseases such as pulmonary fibrosis. Dornase alfa, also known as DNase 1 or Pulmozyme, has received FDA approval for treating cystic fibrosis, aimed at breaking[2] down dense mucus and reducing the risk of lung infections. The next phase involves expanding clinical trials in order to validate these findings and explore Dornase alfa’s role[1] in standard treatment protocols.

Severe COVID-19 pneumonia presents a formidable challenge to healthcare systems worldwide. Characterized by hyper-inflammation and respiratory distress, the condition often requires intensive care and prolonged hospitalization. Since the onset of the COVID-19 pandemic, the mortality rate associated with SARS-CoV-2 infections has significantly decreased. This decline can be attributed to enhanced immunity resulting from prior infection or vaccination, coupled with advancements in treatment strategies. One notable example is dexamethasone, a steroid effective in mitigating hyper-inflammation, which is a critical factor contributing to COVID-19 fatalities.[3] However, it's important to note that while dexamethasone has proven beneficial for many severely ill patients, it may not be suitable for all patients.

Researchers aimed to determine whether Pulmozyme could improve outcomes for 39 patients who were admitted to the hospital with severe COVID-19 pneumonia and who required oxygen. Approximately 30 patients were randomized to receive twice-daily nebulized Pulmozyme. In addition, they would receive the best available care (BAC), which included dexamethasone. The remaining nine patients were randomized to receive BAC only. Measurements for C-reactive protein (a marker of systemic inflammation) levels in the blood were conducted over seven days or until patients were discharged from the hospital. Results showed that patients treated with Pulmozyme had a 33% reduction in systemic inflammation, in addition to the reduction

provided by dexamethasone.[4] Patients who received Dornase alfa required less oxygen and showed quicker discharge rates compared to those who received BAC alone. These added advantages could alleviate the strain on resources and hospital beds in the UK. Dr. Sarah Patel, a member of the research team, explains, “Our findings indicate that dornase alfa is a safe adjunctive treatment, providing a promising option for managing severe COVID-19 pneumonia without introducing significant additional risk.”[1]

Dr. Venizelos Papayannopoulos, lead researcher at the Francis Crick Institute, emphasized, "While dexamethasone has demonstrated considerable success in treating severe COVID-19 pneumonia and is now standard practice in the UK, it may not be suitable for all patients, including those with diabetes..."[2] Dornase alfa's potential extends beyond treating severe COVID-19, and the study’s findings suggest this as well. Shared mechanisms can benefit from its therapeutic effects. Given its mechanism of action in reducing hyper-inflammation, it holds potential for treating other respiratory infections, such as those caused by influenza or bacterial pneumonia, as well as chronic lung diseases like pulmonary fibrosis. This versatility underscores the drug's potential to address a range of respiratory ailments.1

In conclusion, the study's findings show Dornase alfa's dual potential as a critical treatment for severe COVID-19 pneumonia and a versatile tool in managing various respiratory infections and chronic lung diseases. With its ability to reduce hyper-inflammation and improve patient outcomes, alongside its FDA-approved status for cystic fibrosis, Dornase alfa emerges as a promising candidate for broader clinical use.

As ongoing research expands its scope and efficacy, the hope is that Dornase alfa will not only alleviate the burden on healthcare systems during pandemics, but also offer new avenues for treating respiratory ailments, ultimately enhancing patient care and outcomes worldwide.

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6th Year Perspective: Behind the Scenes at Pfizer

Featuring: Simkho Shimonov, PharmD Candidate c/o 2025
By: Rebecca Sabzanov, PharmD Candidate c/o 2026

Simkho Shimonov, a dedicated and diligent PharmD candidate at St. John's University, is set to graduate in 2025. With an extensive background in both retail and hospital pharmacy, he has amassed a broad understanding of the field. Recently, Simkho further diversified his experience through a prestigious internship at Pfizer.

What inspired you to apply for an internship at Pfizer?

My goal in applying for this internship was to broaden my horizons and my understanding of the pharmacy field as much as possible. After gaining experience in private, community, and hospital pharmacy, I took a step back and asked myself, what's next?

What were your main responsibilities at Pfizer? Were there any projects you were involved in?

I was placed as an Intern in the Health Economics and Outcomes Research (HEOR) Oncology pipeline team, and I reported directly to the Senior Director of Oncology. A typical day included joining him in relevant meetings as well as completing any other tasks I was assigned. Due to my background in pharmacy, which was uncommon on the team, my first project included converting different opioid formulations and strengths from an ongoing clinical trial into a single oral morphine equivalent to compare different patients pain levels during different periods of time after treatment was initiated. Other projects included working with statisticians to create charts and graphs to better visualize the adverse effect profile of clinical trial data. In my free time, I joined other meetings set up for the summer interns and fun activities that were planned for us.

What was the application and interview process like?

The application submission process was fairly simple. I filled out an application online and wrote a 500-word paragraph as to my motivation for applying for the intern position. Afterwards, I received a call and answered questions which focused on my background, interests, and reasons for applying to Pfizer. The interview process consisted of my education level, my past experiences, skills, how well I work in a team, and real-life problem-solving examples. Then, I was emailed an offer and began onboarding shortly after.

How has this internship at Pfizer influenced your career goals and aspirations?

The internship opened my eyes to the pharmaceutical industry. Unfortunately, this is something our core classes don't teach us much about. It helped me understand that there is an alternative pathway besides community and hospital pharmacy. It feels like another door has opened for me in deciding on a career in the near future, one that, to me, feels more intellectually stimulating.

How did your academic knowledge prepare you for the internship? Were there any specific courses or programs that helped most?

Being a pharmacy student and having knowledge and understanding of various drugs and the effects they have on our patients came in handy during the internship. Taking the Drugs and Diseases course in Oncology definitely helped me understand many of the breast cancer drugs I was working with on the pipeline team. Being fluent in the opioid conversion was also a huge plus. I don't want to admit this because I did not find it to be the most interesting class, but the course on Drug Literature and Design was by far the most important when it came to completing the projects I was assigned. Understanding statistical significance, P-values, and hazard ratios was critical and was utilized every day.

What advice would you give younger PharmD students considering an internship at Pfizer?

Go for it! There is quite literally nothing to lose and everything to gain. You either fall in love with the experience, or you figure out that it isn't for you. Every day during the internship, I got to learn something new - whether it was groundbreaking data from a clinical trial or seeing the business aspect of industry such as competitor products, appealing to different agencies, and how it affects trial design. It was also a great networking opportunity as you get to meet people from all different backgrounds, all around the world.

Meet the 2024-2025 Team Members

Editorial Team & Production

Anjali Thykattil
Editor-in-Chief

The Rho Chi Post serves as both a creative and educational platform that allows students and faculty to collaborate in sharing their knowledge with the pharmacy community. Unlike other pharmacy organizations at St. John's, it also allows for the unique experience of expanding research and writing skills outside of the classroom setting. As pharmacy students, it is imperative we continue to educate ourselves as the world of healthcare is ever-changing. I am honored to be a part of the Rho Chi Post's Editorial Team and look forward to serving as this year's Editor-in-Chief!

John Ortiz
Managing Editor

Rho Chi Post is an opportunity for students to foster their writing and investigative skills concerning the pharmacy practice. Through Rho Chi Post, students are also exposed to novel information and perspectives that are present in the pharmacy community and in our own student body. By honing our understanding of new innovations and developments in pharmacy, we will be better adept at providing accurate information to readers and maintaining the continuous education expected of pharmacists.

Bao Qi Chen
Senior Content-Focused Copy Editor

The Rho Chi Post is a bridge between students and the world we will soon enter once we graduate. My ambition is to promote intellect, values, and opportunities that not only allow students to be heard but also impact the pharmacy profession as a whole. I am honored to be a part of the Rho Chi Post's editorial team and work with colleagues who share this ambition. I am excited and grateful for this opportunity, and I look forward to working with everyone!

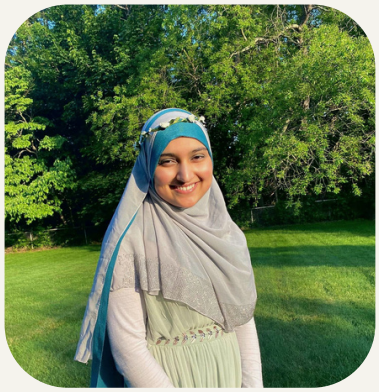
MEET THE TEAM

Warda Basher
Senior Content-Focused Copy Editor

Joining this esteemed team excites me with the opportunity to gain invaluable experience and insights into the latest trends in pharmacy. I am eager to expand my professional network and make significant contributions to the field. As a member of the editorial team, I'll be at the forefront of disseminating the most current news and knowledge, effectively impacting pharmacy professionals worldwide with timely and relevant information.

Ramesa Anan
Content-Focused Copy Editor

Being in the Rho Chi Post means being part of an environment that allows me to grow both academically and professionally in the field of pharmacy. It means being able to participate with like minded individuals who strive to grow in the field of pharmacy by publishing newsletters with relatable and useful content. I hope to contribute to the continuing success of this student-operated newsletter and aid my team to the best of my ability.

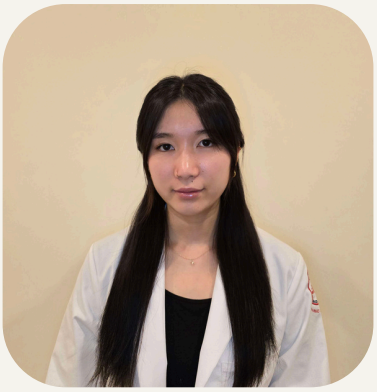


Sameeha Arshad
Content-Focused Copy Editor

To me, being a part of the Rho Chi Post means being part of a community that values knowledge sharing, collaboration, and making a positive impact in the field of pharmacy. It provides me with a platform to contribute meaningful insights, engage with fellow pharmacy students, and inspire others through informative articles and discussions. The opportunity to be a part of this publication is both rewarding and enriching, allowing me to grow professionally and connect with a diverse audience passionate about pharmacy and healthcare.

Amanda Kim
Content-Focused Copy Editor

Being part of the Rho Chi Post means having the opportunity to help actively contribute to the advancement of the pharmacy profession. As an editor, I will be able to enhance my own writing, be inspired, and share the new innovations/issues within healthcare with my peers. I am very excited to join the team this year!



MEET THE TEAM

Laiel Bravo
Content-Focused Copy Editor

The Rho Chi Post has been a segway for pharmacy students to immerse themselves in valuable research work, advancements, and issues within the field. As future pharmacists, it is important to be informed of the latest news and gain insight from the experiences/ideas of others so that we are equipped to further improve the healthcare system. I aspire to use this opportunity to not only enhance my own preparedness but also to help enhance my peers in being ideal professionals who provide exemplary care to patients.

Zainab Masood
Senior Graphics-Focused Copy Editor

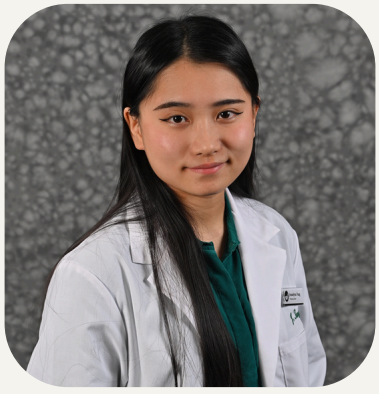
Being part of Rho Chi Post, which provides information on discoveries and research to others, is an honor. Taking insight from professionals and peers to educate others is a rather significant effort in the expanding and evolving role of pharmacists. I look forward to collaborating with the team in pushing this effort further while also learning from them.

Nalisha Xu
Graphics-Focused Copy Editor

By becoming a part of the Rho Chi editorial team, I wish to learn more about the pharmacy field and community by gaining insight through our publications. This position will not only allow me to broaden my views on the profession of pharmacy, but also explore topics related to the medical field as a whole. Through Rho Chi's team, I will utilize this experience to grow professionally, develop leadership skills, and be more involved in our community to improve my confidence and professionalism on my journey to becoming a pharmacist.

Jennalynn Fung
Senior Staff Editor

I am thrilled to have the opportunity to express my creativity, critical thinking, and research skills through contributing to the Rho Chi Post. The mission to promote intellectual discourse and showcase diverse perspectives aligns with my values; I look forward to putting my writing and editing experience to use in each issue, and hope that my involvement can ensure that future cohorts will also have this valuable platform available to them.



MEET THE TEAM

Sharupa Azmal
Senior Staff Editor

The Rho Chi Post serves as a notable forum for pharmacy students who wish to expose themselves to medical journalism. Being a staff editor of the Rho Chi Post means amplifying the voices of our writers and educating our readers regarding current events in healthcare. This role provides me with the opportunity to present insightful stories that are relevant to the pharmacy community and contribute to the advancement of the profession through writing.

Anya Geiling
Staff Editor

Hello! My name is Anya, and I am very grateful to be a part of Rho Chi Post. As a rising Sophomore studying Nursing, I have a passion for understanding and sharing research about the medical field. I am ecstatic to be able to utilize my editing skills to assist with medical-related articles.

Wajiha Uddin
Staff Editor

The Rho Chi Post is a robust community of pharmacy students that are dedicated to fostering growth and sharing newest technologies and innovations in pharmaceutical practice. Being part of the Rho Chi Post means being involved in the supportive network of peers that share a passion for pharmaceutical education, practice, and the drive for contributing to the advancement of pharmaceutical knowledge.

Christiana Popovic
Staff Editor

As a member of the Rho Chi Post, I would be part of a professional community that shares insights, advancements, and challenges within the field of pharmacy. The Rho Chi Post not only empowers and educates, but it shapes the future of pharmacy through its engaging and concise writing.

MEET THE TEAM

Christine Mauceri
Senior Staff Writer

Every student deserves a voice, and to me, being a part of the Rho Chi Post allows us to make that voice heard. Whether it's through opinion pieces, talking about personal experiences, or educating on new pharmacy advancements, this newsletter sticks to its mission of promoting the pharmacy profession. As a Staff Writer, I am excited to learn, grow, and make meaningful contributions to the profession!

Rand Ayoub
Staff Writer

Being in Rho Chi Post gives us the opportunity to shed light on crucial topics within healthcare to the St. John's Community. By using the skills and information given to us in our academic classes, this organization offers a chance for people to build on those skills and be able utilize them for the better. I look forward to contributing to Rho Chi Post as well as learning from an amazing group of people!

Nivaj Haque
Staff Writer

Joining the Rho Chi Post will allow me to merge my analytical skills with my passion for public health, within the rapidly evolving field of pharmacy. This role helps keep us at the forefront of pharmacy innovations and enables me to contribute to keeping our pharmacy community well-informed. I'll explore new research and policy changes, aiming to enhance our collective understanding and application of pharmacy practices that positively impact patient care and healthcare delivery. I'm excited about starting this role and engaging in discussions that shape the future of our profession.

Rebecca Sabzanov
Staff Writer

Being part of Rho Chi Post is an exciting opportunity for me to merge my passions for writing and pharmacy in a prestigious organization. I'm enthusiastic to contribute to such a respectful organization and collaborate with other members of the Rho Chi Post to produce meaningful content that will impact others.

MEET THE TEAM

Ameena Qadri
Staff Writer

Being a member of the Rho Chi post means a great deal to me because it is the perfect outlet for me to write about pharmacy related topics that interest me the most. I feel that the Rho Chi post will also allow me to develop my writing skills both professionally and creatively. I sincerely appreciate your consideration and I am looking forward to joining the team!

Michelle Flores
Staff Writer

My name is Michelle Flores and an incoming fourth year pharmacy student. Having the opportunity to be a Staff Writer gives me the chance to educate others about pharmacy news. Pharmacy is a field that is constantly evolving and as future pharmacists, it is our responsibility to continue learning. Maintaining current knowledge benefits not only our patients but also enriches our own expertise. I'm thankful and excited to be a part of Rho Chi Post as a Staff writer this upcoming year!

Amanda Nakhul
Staff Writer

Hello! My name is Amanda Nakhul, I'm a rising sophomore and biomedical sciences major. I'm rather new to St. John's, so being a part of a high-quality collaborative organization such as the Rho Chi Post means the world to me. As a Staff Writer I am able to incorporate my passion for writing with my appreciation for Pharmacy and medicine. The Rho Chi Post provides a foundation for student-operated publications and it is an honor to be included in this journey.

Royal Mussaleen
Staff Writer

As a member of the Rho Chi Post, I see this as an opportunity to enhance the pharmacy profession. By highlighting the diverse roles pharmacists play; from ensuring medication safety and efficacy, conducting research, advocating for patient safety, to analyzing healthcare trends like telepharmacy and personalized medicine, and advancements in gene therapy and immunotherapy; I aim to showcase the impact pharmacists have on society's well-being. I intend to offer engaging perspectives on pharmaceutical developments, healthcare policy changes, and the role of pharmacists in regulatory affairs. Through my contributions, I hope to spark curiosity in our readers to explore the underlying reasons and mechanisms behind these processes.

MEET THE TEAM

Ariella Zadrima
Staff Writer

As a pharmacy student and future pharmacist, I believe it is a quintessential duty to educate ourselves on current media regarding the medical field and continuously adapt to the new ideas we may face as we enter the pharmacy profession. With topics from emerging diseases to scientific advances made, it is important to be accustomed to new ideas that pertain to our potential responsibilities as a pharmacist. As a Rho Chi Staff Writer, I hope to discuss matters that will inform not only pharmacy students but the St. John's community as a whole on topics that have to do with general health and scientific developments. With my interest in writing and the pharmacy field, I hope to touch upon subjects passionate to me that can benefit our community and inspire our readers to integrate themselves into the ever-growing profession of pharmacy.

MEET THE TEAM

Social Media & Outreach

Maliha Akter
Engagement & Outreach Manager

In my pursuit of becoming a knowledgeable and skilled pharmacist, I remain committed to staying informed about disease treatment and public-health policy. Being a part of Rho Chi Post provides an excellent platform for continuous education and knowledge-sharing with peers. Engaging with individuals from diverse backgrounds fosters critical viewpoints and discussions, all focused on enhancing patient-centered care. Additionally, the newsletter enables me to nurture my lifelong passion for writing while staying updated on the latest healthcare developments. As I embrace this transformative journey, I am dedicated to adapting, learning, and making a positive impact on patient well-being as a compassionate and competent pharmacist.

Bhojranie Brahmanand
Engagement & Outreach Manager

The Rho Chi Post uses its platform to spread knowledge of groundbreaking discoveries that are changing the standard of care for society. It delivers a creative and innovative scope of the pharmacy world. As a school of pharmacy, it is pivotal to become aware of healthcare matters. In turn, we can strengthen our understanding of the field and become more competent pharmacy practitioners. I am excited to be joining the team this year as a staff writer. I look forward to working alongside like-minded individuals in cultivating writing pieces that will share the importance of this profession.

Paulina Maczko
Engagement & Outreach Manager

As pharmacy students, I believe we have an obligation of staying informed on current healthcare topics, topics that the Rho Chi Post sheds light on. To be part of such a team is an honor, as students are granted the opportunity of a creative outlet, whether that is by writing the articles or organizing the newsletter. As a copy editor, I look forward to seeing first-hand how students voice their opinions, thoughts, and academic learnings. I'm grateful to be part of a team that allows students to understand what they are capable of, and simultaneously advance their writing, comprehension, and communication skills.

Social Media & Outreach

Celestine Van Sertima
Engagement & Outreach Manager

When applying to the Rho Chi Post, I was initially fascinated by their goals of providing the highest quality of information to the St. John's community through a student operated newsletter that cultivates both student spirit and expansion of knowledge. Through my passion for writing and health care, combined with my experience in graphic designing, I look forward to what I can contribute to the Rho Chi Post.

MEET THE TEAM

Advisors

Dr. Ketan Patel
MPharm, PhD

It is an honor to serve as a faculty advisor of Beta Delta Chapter of a 100-year-old prestigious society of pharmaceutical professionals – The Rho Chi Society. With great enthusiasm, I am committed to assist the Rho Chi member's endeavors in: (1) disseminating the latest information/technology in healthcare system; (2) promoting pharmaceutical field & career propulsive networking of current students, alumni, and faculties; and (3) facilitating the scholastic activities and recognizing the scholars.

Dr. Joseph Etzel
BS Pharm, PharmD

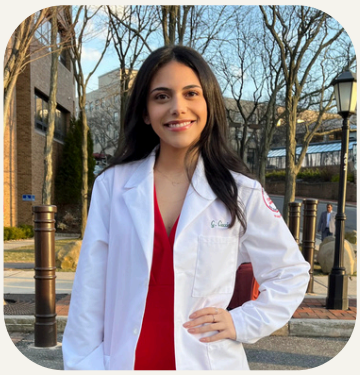
Dr. Etzel served as the Rho Chi Post's interim faculty advisor for the 2022-2023 academic school year and continues to aid the Rho Chi Honor Society as we welcome in our new advisor. Dr. Etzel is not new to our organization, as he has previously served as the faculty advisor for the Rho Chi Honor Society. He has been a huge influence to the success of Rho Chi in the past, and we look forward to continue working with him!

Dr. Mohammad Rattu
PharmD, BCOP, BCPS, BCGP

I am thankful to have been the 2012 editor-in-chief of the Rho ChiPost newsletter, as well as on the 2019 alumni honor roll of the national Rho Chi organization. This is one of the most successful longitudinal projects at my alma mater, as evidenced by its decade-long persistence and teams of highly-motivated students. I remain available for professional support and assistance with the new year's initiatives.

The Rho Chi Society

Executive Board



Geraldine Ciaccio
President

The Rho Chi Society prides itself on fostering intellectual achievement and cultivating professional development. It provides opportunities for students, faculty, alumni, and colleagues to expand their knowledge of pharmacy practice. Through events, seminars, and fundraisers, Rho Chi allows pharmacy students to develop leadership skills that are vital to the profession. I have learned valuable lessons about pharmacy and myself from Rho Chi thus far, and I am honored to be able to give back to the organization. I am humbled to hold such a position and work with a dedicated executive board.

Javeria Amir
Vice President

The Rho Chi Society is an organization that contributes to the development of intellectual leaders in pharmacy. Through this, Rho Chi Society fosters collaboration and initiatives to advance learning in the field of pharmacy. Being part of this organization has allowed me to reach out for help when needed, and continuously improve my skills as a future pharmacist. To be a part of the executive board that will continue to uphold these initiatives is an honor and responsibility I take on with pride. Wishing all a wonderful and successful academic year ahead of us!

Anjali Rana
Secretary

Being a part of Rho Chi has provided me with invaluable opportunities for professional development, connection, and mentorship. The society's commitment to academic excellence and ethical pharmacy practice has inspired me to strive for continuous improvement in my studies and future career. Serving on this year's executive board, provides a sense of belonging among a supportive and inclusive community.

Giavanna Carr
Treasurer

The Rho Chi Honor Society encourages and recognizes intellectual achievements, stimulates critical inquiry in order to advance the future of pharmacy, provides its members with the ability to develop into intellectual leaders, promotes high ethical standards for its members, and fosters collaboration. Through being a member of Rho Chi, we are able not only to grow ourselves, but to help uplift our colleagues and allow them the chance to excel academically through the events we provide. Rho Chi has been a great influence on my studies during my time in this program and being given the opportunity to serve on the executive board allows me to become the influence for the younger students in our program. I'm inspired by every member of this years executive board and can't wait to see all we're able to accomplish together this year!

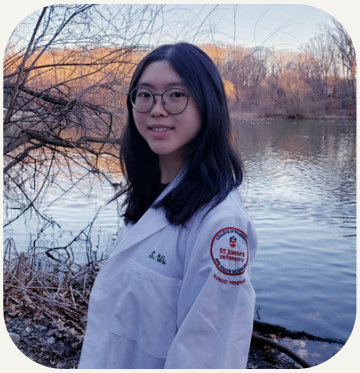
The Rho Chi Society

Executive Board

Christine Mauceri
Historian

Rho Chi is an amazing organization that encourages leadership and support among its members. Not only does it offer a space where all pharmacy students can help each other academically, but the opportunities for networking and professional growth are endless. I am proud to be a part of an organization that has helped me immensely throughout my studies, and I am excited to give back to my pharmacy community!

Sammi Wu
Development and Outreach Coordinator



The Rho Chi Society is committed to the development of future pharmacists that excel in both areas of professional expertise and acts of service. It forms a community for pharmacy students to motivate each other's academic growth and provide support within a challenging degree program. It also keeps students informed on news related to breakthroughs in drug therapy and patient care. I am honored to accept my position on the executive board for this upcoming academic year and I hope to fulfill my duties so Rho Chi can continue to have its positive impact on the pharmacy profession!

Daya Biju
Academic Committee Chair

The Rho Chi Honor Society is a distinguished academic organization that recognizes excellence in pharmaceutical studies. It promotes ethical conduct, leadership, and research in pharmacy education. With chapters across the United States, Rho Chi fosters a sense of community and offers valuable networking and mentorship opportunities. Members actively engage in service projects to improve public health awareness. I am truly honored to serve this esteemed organization and embrace the opportunities it offers for personal and professional growth.

Angel Gao
Academic Committee Chair

Rho Chi fosters a community where students can collaborate with each other, upholding the core principles of service and professional development. Being a part of this supportive community is an honor, and I take pride in contributing to the culture of excellence that Rho Chi cultivates.