

RHO_{Rx}CHI

post

VOLUME 2, ISSUE 8

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

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A WORD FROM THE EXITING CO-EDITORS-IN-CHIEF - GOODBYE!

Dear Readers,

The past two years have been an exciting opportunity for us as editors and, more recently, as Editors-in-Chief of the Rho Chi Post. Your contributions, comments, and articles have inspired and enabled us to set a high standard for student publication platforms across the nation.

We want to take this opportunity to thank the wonderful fellow classmates and Doctors of the Class of 2013 at St. John's University College of Pharmacy and Health Sciences. We want to thank Dr. S. William Zito for being extremely supportive of the Rho Chi Post and for being an inspiration to all of us. We are grateful for the faculty members and administrators at the College of Pharmacy and Health Sciences for their continuous support and advice. Last but not least, we want to thank you, our readers, for making this possible. Without your contributions, feedback, and comments, we would not be where we are today. Please continue to be active with the Rho Chi Post, and we hope you will honor the 2013 Editorial Team the same way you have honored us. Once again thank you to everyone and congratulations to PharmD Class of 2013.

Sincerely,

Steve Soman and Neal Shah

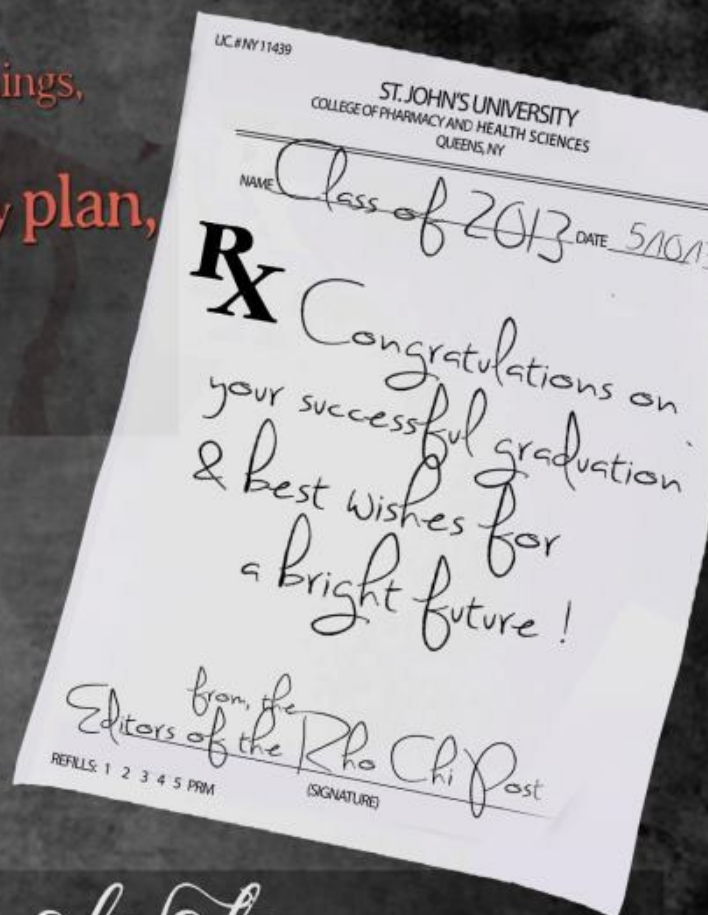
Immediate Past Co-Editors-in-Chief

Single Line Stories

- Congratulations to the Doctor of Pharmacy Class of 2013! -
- Did you know that we also publish during the summer months? -
- Follow us on Twitter @RhoChiPost and on Facebook: FB.com/RhoChiPost -

To accomplish **great** things,
we must not only act,
but also dream. Not only **plan**,
but also **believe**.

-Anatole France



*Congratulations,
Pharm D. Graduates!*

CLASS OF 2013

AUVI-Q™: THE NEWEST EPINEPHRINE DEVICE TO HIT THE MARKET

BY: DIANA GRITSENKO, STAFF EDITOR

Most of us who work in a community pharmacy setting will usually get a few scripts a month for an Epi-pen™. An Epi-pen™ is a device that autoinjects epinephrine (also known as adrenaline) into a patient who is experiencing anaphylaxis. Anaphylaxis is a severe, whole-body allergic reaction to a foreign substance or an allergen.¹ This device can be life-saving as it can reverse or relieve some of the effects of anaphylaxis such as a dangerously low blood pressure, tightening of the lung muscles (which causes wheezing), and swelling of the throat and face.² However, patients can put themselves in danger because they may not be aware of how to use the Epi-pen™ and may not even carry it around. A new autoinject device, the Auv-Q™, has entered the market and promises to provide ease-of-use and better portability for patients.³

When the Epi-pen™ autoinjector is dispensed in a pharmacy, it is packaged in a box that contains two live Epi-pens and a practice dummy without a needle. When patients experience symptoms of anaphylaxis, they are instructed to grip the Epi-pen™ with the needle end (characterized by its orange tip) pointing downwards towards the floor, remove the blue safety cap on the top side of the pen, and stab the pen firmly into the muscle of their outer thigh. The force of the impact retracts the orange tip and exposes the needle which delivers the epinephrine into the muscle. In order to ensure that all of the epinephrine has been delivered, the patient has to hold the pen in place for approximately 10 seconds.⁴

Patients are counseled by their doctor or pharmacist on how to use this device. However, in stressful emergency situations, patients commonly forget the counseling points they might have received some time ago. The directions are written on the back of the pen itself, but it is unlikely that a patient will read them when in a state of panic. Furthermore, patients are supposed to carry this device with them everywhere in case of an emergency. Unfortunately, the size of the Epi-pen™ may discourage patients; the device resembles a large felt-tip marker, and as of September 2012, each one comes in its own carrying case.⁵ These are the issues that the

Auvi-Q™ was built to address.

The Auv-Q™ was the brainchild of Eric and Evan Edwards. The twins grew up with serious food allergies and were instructed by their doctor to always carry the Epi-pen™ around. As they grew older, they found this advice increasingly hard to follow. After college, Eric Edwards pursued a career in Pharmaceutical Sciences and Evan Edwards received a degree in Engineering; they combined their talents to create the new device which hit pharmacy shelves this year.³

The Auv-Q™ has a similar needle length, gauge and injection force to that of Epi-pen™. Auv-Q™ also injects 0.3mg of epinephrine and has similar peak and total epinephrine levels according to a randomized, crossover, bioavailability study. The advantage of the Auv-Q™ lies in its design.^{5,2}

This new device is about the length and the width of a credit card and as thick as a smartphone. It can easily slip it into a pocket or be carried around in a purse. In order to use the autoinjector, the patient has to first pull off the outer case of the Auv-Q™. When this case is removed, the device beeps and begins to dictate the instructions to the patient. Similar to the Epi-pen™, the Auv-Q™ has a safety cap that needs to be pulled off in order to activate the needle. The difference lies in the color of the Auv-Q™ safety cap (red) and its location (over the needle). The patient is then instructed to place the black end of the device over his or her outer thigh and press firmly for 5 seconds (as opposed to 10 seconds for the Epi-pen™). Auv-Q™ counts down the 5 seconds and instructs the patient to seek emergency medical attention right away.⁷

The Epi-pen™ and the Auv-Q™ are both used for anaphylaxis and contain 0.3mg of epinephrine. The difference between them lies in the mechanism of drug delivery. The makers of Auv-Q™ claim that their product is made from real-world experiences and feedback from the patients and their caregivers. Eric and Evan Edward believe that this gives them an advantage over the traditional Epi-pen™. Since this device was made available in the United States on January 28, 2013, it is too soon to tell how the Auv-

QTM will fare in the market; but it is a product pharmacists should keep an eye on and appropriately counsel patients on.⁸

SOURCES:

1. Anaphylaxis. National Institute of Health Web site. nlm.nih.gov/medlineplus/ency/article/000844.htm. Updated May 30, 2012. Accessed March 1, 2013.
2. Epi-pen: Frequently asked questions. Epi-pen Web site. www.epipen.com/about-epipen/faqs. Updated 2013. Accessed March 1, 2013.
3. Thomas K. Brothers develop new device to halt allergy attacks. *New York Times*. February 1, 2013.
4. Epi-pen: How to use Epi-pen. Epi-pen Web site. <http://www.epipen.com/how-to-use-epipen>. Updated 2013. Accessed March 1, 2013.
5. Newly designed Epipen. Allergy UK Web site. www.allergyuk.org/news/latest-news/post/42-newly-designed-epipen. Updated September 12, 2012. Accessed March 1, 2013.
6. In brief: Auvi-Q- A new epinephrine auto-injector. The Medical Letter Online Web site. www.secure.medicalletter.org/w1410a. Updated 2013. Accessed March 1, 2013.
7. About Auvi-Q. Auvi-Q Website. www.auvi-q.com/auvi-q-demo. Updated 2013. Accessed March 1, 2013.
8. Auvi-Q is now available in the US. Intelliject Web Site. www.intelliject.com/2013/01/29/auvi-q-tm-is-now-available-in-the-us. Updated January 2013. Accessed March 1, 2013.

PLAN B[®] PILL AVAILABLE TO WOMEN 15 YEARS OF AGE AND OLDER

BY: BANSRI PATEL, PHARMD CANDIDATE C/O 2016

As of May 1st 2013, Plan B[®], the brand name emergency contraception pill will now be available to women aged fifteen and older. It will also be sold in the drug store aisles, as opposed to its current location behind the pharmacy counter.

When levonorgestrel (Plan B[®]) first entered the market, its purchase was restricted to those over seventeen years of age. This drug is shrouded in controversy because many believe it to be an abortifacient. However, levonorgestrel does not precipitate an abortion but rather prevents ovulation or fertilization by altering tubal transport of sperm and/or ova. If the egg has already reached the uterus, levonorgestrel prevents the egg from latching onto the uterine wall. Side effects include nausea, abdominal pain, and menstrual changes. Levonorgestrel does not harm an existing fetus, nor does it prevent an existing pregnancy. It also cannot prevent sexually transmitted diseases and HIV. Levonorgestrel is not meant to be used routinely as a means of birth control.¹

Plan B[®] has been proven to be safe and effective in women aged seventeen and older, but it is also expected to have the same safety and efficacy when taken by post-pubertal adolescents younger

than 17.² Professional groups, such as the American Association of Pediatrics, have advocated the use of levonorgestrel in a younger population. As promulgated in AAP's official stance on Emergency Contraception for Adolescents, "The AAP encourages abstinence plus comprehensive sexuality education as the best way to help prevent unintended pregnancy and sexually transmitted diseases. Ensuring access to contraception - including emergency contraception - and educating sexually active adolescents on proper use and indications of the various methods are essential components to comprehensive sexuality education."³

In 2011, Kathleen Sebelius, the secretary of Health and Human Services overrode the FDA's decision to make Plan B[®] over the counter and without age restriction. Her verdict was based on the lack of sufficient evidence to prove that the pill was safe for girls aged fifteen and younger and the uncertainty that adolescents in this age group were capable of fully understanding how to use the medication. Many adolescents reach puberty at the age of eleven, and she cited "significant cognitive and behavioral differences" between older adolescents and "the youngest girls of reproductive age."⁴ One specific concern was that young girls would inappropriately use levonorg-

estrel for routine birth control instead of its intended use in emergency situations. Furthermore, levonorgestrel carries the risk of being misconstrued as a means of STD prevention.. Kathleen Sebelius's decision retained levonorgestrel's status as only available to women aged 17 and older without a prescription. Any women below the age of seventeen would need a prescription from a physician to obtain the medication.⁵

In 2012, Teva, the pharmaceutical company that manufactures Plan B[®], filed an amended New Drug application that would allow access to fifteen year olds. Margaret Hamburg, the FDA commissioner said, "The data reviewed by the agency demonstrated that women 15 years of age and older were able to understand how Plan B One-Step[®] works, how to use it properly, and that it does not prevent the transmission of a sexually transmitted disease."⁶ Teva submitted a study and label comprehension data showing that females in this age group were able to comprehend how the medication was to be used and did not need a healthcare provider's approval to take the medication. The new Plan B[®] labels will now state that females aged fifteen and older may take the emergency contraceptive with proof of identification.⁶ Kathleen Sebelius indicated that she is now comfortable with FDA's decision to lower the age limit, as there is now sufficient evidence to prove that adolescents aged fifteen and older have the cognitive capacity to understand directions for the appropriate use of levonorgestrel. President Obama has also backed FDA's decision. He issued a statement in a recent press conference, "The rule that's been put forward by the FDA, Secretary Sebelius has reviewed. She's comfortable with it; I'm comfortable with it".⁷

In a recent court ruling, Federal Judge, Edward R. Korman, of the Eastern District of New York, ruled that levonorgestrel or Plan B One Step[®] should be sold without age restrictions. He claimed that the Obama Administration's previous decision to limit the access of the medication was politically charged and had no scientific backing. He accused the Obama Administration of choosing politics over science. During this time, the FDA was still reviewing Teva's application to market Plan B One Step[®] to those aged fifteen and older and the FDA's decision to lower the age was not associated with the court order.¹ The

Obama Administration has decided as of May 3, 2013, that it will appeal the Judge's decision.⁷

SOURCES:

1. Full Product Information. Plan B One-Step. <http://www.planbonestep.com/pdf/PlanBOneStepFullProductInformation.pdf>. Accessed May 3, 2013.
2. Taylor, Amy M., MD, MHS. Pediatric Focused Safety Review: Plan B One-Step Pediatric Advisory Committee Meeting January 30, 2011 <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM289946.pdf>. Accessed May 4, 2013.
3. AAP Issues New Statement On Emergency Contraception For Adolescents. American Academy of Pediatrics. <http://www2.aap.org/advocacy/releases/sept05contraception.htm>. Updated 2012. Accessed May 3, 2013.
4. Kendall B, Anderson M. Restricted Access to Plan-B Pill Overturned. *The Wall Street Journal*. April 9, 2013. <http://online.wsj.com/article/SB10001424127887324600704578404393383162004.html>. Accessed May 4, 2013
5. Belluck P. Drug Agency Lowers Age For Next-Day Birth Control. *The New York Times*. April 30, 2013. <http://www.nytimes.com/2013/05/01/health/fda-lowers-age-for-morning-after-pill.html?src=recg&r=0>. Accessed May 4, 2013
6. FDA approves Plan-B One-Step emergency contraceptive without a prescription for women 15 years of age and older. News & Events: FDA News Release. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm350230.htm>. Updated April 30, 2013. Accessed May 3, 2013.
7. O'Brien M. Obama 'comfortable with FDA's lowered age limit for 'Plan B.' First Read on NBCNews.com http://firstread.nbcnews.com/_news/2013/05/02/18023867-obama-comfortable-with-fdas-lowered-age-limit-for-plan-b?lite. Updated May 2, 2013. Accessed May 4, 2013.

with sincere prayers and deeply felt sorrow,
the editors & staff of the Rho Chi Post

express our condolences
to the family and friends of

Janet Mangione

Wife of

Dr. Robert Mangione, R.Ph.
Provost and Professor of Pharmacy
Office of the Provost

and

Mother of

Robert M. Mangione
Assistant Dean and Manager of Operations
Financial Information Lab
The Peter J. Tobin College of Business

In lieu of flowers, please donate to the
Janet E. Mangione Endowed Scholarship for
Academic Service Learning
via the Office of Institutional Advancement.

EVENT REVIEW: RELAY FOR LIFE

BY: RACHNA BURMAN AND RADASHI RAHMAN, PHARM D CANDIDATES C/O 2016

Relay for life (Relay) is a volunteer-based fundraiser to support cancer research by the American Cancer Society. Each April, students of St. Johns University participate in this event. Relay is a poignant event in which students who are either directly or indirectly affected by cancer can honor their loved ones and help make a difference in the fight against cancer. It also showcases the University's Vincentian values of serving the community.

Our involvement in this event as freshmen and as sophomores inspired us to take on the position of fundraising chair for Lambda Kappa Sigma (LKS) this year. It is always inspiring to see the large number of students who come out to support such a wonderful cause each year. Our team—thanks to sponsors such as Johnson & Johnson® and Home Depot®—raised over \$16,000. A large amount of donations also came from several alumni who participated in the event this year.

Fundraising for a good cause is a rewarding experience. Over the years, LKS has raised money by

holding events such as Rose Sales for Valentine's Day, karaoke dinner, nail painting, bake sales, and candy sales. Even faculty members have shown support by coming to our sorority's events. Still, for LKS, Relay has held a special place for the past eight years as a fund-raiser, especially since some of our alumni have been personally affected by cancer.

This year's theme was called "Carnival of Hope," which was quite different from those of previous years in that the Relay itself had several fundraisers within the event. Another fun component that was incorporated this year was a student-performed comedy show. All the other details aside, 118 teams and 1,509 people took part and raised over \$100 000 to support cancer research this year. And even though many participated this year, more are always welcome. Relay for Life is something that every student should get involved in at some point in their academic career at St. Johns, because it is a great way to support the fight against cancer, to bond with fellow students and faculty, and to show some school spirit.



All photos for this article were contributed by Rachna Burmen, PharmD Candidate c/o 2016

Share your Rotation Experiences!

Email us at rhochipost@gmail.com

COLLEGE OF PHARMACY AND HEALTH SCIENCES HOSTS YEAR-END BBQ EVENT

BY: TASNIMA NABI, SENIOR STAFF EDITOR

On May 2nd, St. John's University College of Pharmacy and Health Sciences hosted the "Pre-Finals Relax, Refresh, Recharge Luncheon" on the Great Lawn. The event took place from 12:00 pm till 3:00 pm, with an array of activities. Students were able to picnic on the Great Lawn with a BBQ buffet and ices from the Kona Ice truck, and relax as personal massage therapists worked out any knots from studying. People even got a chance to "Dunk the Deans & Faculty." There were also plenty of giveaways sporting the new College of Pharmacy and Health Sciences' name and different prizes from various information tables. Over a thousand students and faculty attended the event, which was surely a great stressbuster right before the start of finals week.

The Pre-Finals BBQ was coordinated by Associate Dean Sawanee Khongsawatwaja, who shared that the Dean's Office wanted to make sure students were prepared to study for finals week. She commented, "We know finals are stressful, so we wanted to do something fun to get everyone's mind off of all the studying." The event was definitely a success, with over 98% positive feedback gathered from the survey that was e-mailed out by the Dean's Office.

Besides being a relaxing event, the Luncheon also raised money for a good cause. Three "STJ Pride" packages were raffled off for a dollar, which included a Johnny-the-Thunderbird stuffed toy, a St. John's University photo frame, a coffee mug, a planner, and a hoodie. As they enjoyed the food and kept cool with ice cones, the students gathered into a large crowd around the dunk tank, where Dr. Conry, Dr. Martino, Dr. Etzel, and Dean Zito took the wet seat. It was nice to see everyone, faculty and students, together in this pleasant setting. The proceeds from the dunk tank and the raffle were donated to the "Janet Mangione Service Learning Scholarship Fund."

When the idea of a dunk tank was discussed, Dean Zito eagerly volunteered, to join in on the fun. The students and faculty were delighted by his par-

ticipation in the activity. Characterizing the event as "absolutely terrific," Dean Zito said that the College of Pharmacy and Health Sciences would definitely like to make this an annual pre-finals event. He also thanked Mrs. Khongsawatwaja and the staff that helped, including Anthony Marziliano, Gina Lapan, Frances Buscemi, and all the volunteers that participated in the dunk tank. Dr. Zito expressed his hope that such activities are held in the future as well, to raise money for a cause that the senior class can choose.

As the year ends, the College of Pharmacy and Health Sciences urges all students and faculty to fill out the e-mail surveys so they know how to improve for future events. In addition, students and faculty can post feedback on the College of Pharmacy and Health Sciences' Facebook page. From the turnout and memories created, it is clear that the Pre-Finals BBQ was a fun time for all. It is comforting that everyone in the College of Pharmacy and Health Sciences can look forward to future events that are exciting and stress-free.



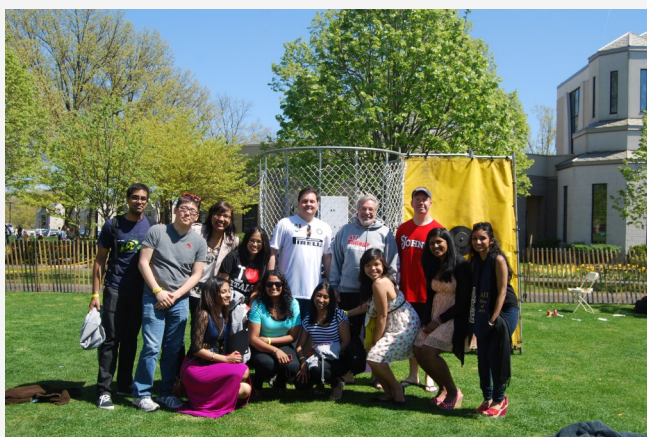
Acting Dean, Dr. Zito, sharing a moment of laughter during the "Dunk the Dean & Faculty" event



Students showing the St. John's Pride! Go Red Storm!!



Nothing quite like some tasty, "comfort foods"



Dr. Zito, Dr. Etzel, and Dr. Conry with PharmD Class of 2013 students after the festivities were over



Clinical faculty members with members of the PharmD Class of 2013



Nothing quite like dropping into a tank of cold water during a nice warm day



Student pharmacists enjoying food and having a great time with faculty members

EVENT REVIEW: PHARMACY DAY

BY: HELEN DONG, PHARM D CANDIDATE C/O 2014

Pharmacy Day, or Legislative Day, is a whole day affair for student pharmacists to meet and speak to members of the federal and state legislature in order to discuss issues that affect pharmacists and to lobby for our profession. This year's talking points were expanding immunization rights and collaborative drug therapy management (CDTM). CDTM allows pharmacists and doctors to work together to create a therapy protocol that allows pharmacists to evaluate, initiate, modify, or continue pharmacologic therapy for patients. CDTM may give doctors' more time to focus on the cases that are acute and complicated—and thus warrants more attention—instead of managing routine chronic illnesses. Currently, only a few teaching hospitals in New York are authorized for CDTM.

Last month, over 40 PharmD students of all years and faculty members traveled to Albany for Pharmacy Day. The day started with a few students from each of the seven NYS pharmacy schools gathering in one room. Everyone was wearing his or her white coat and from the number of attendees, I could see that the field of pharmacy can both be vast and very intimate.

I would never have gone to Albany for Pharmacy Day if it wasn't for the strong recommendation from Dr. Vibhuti Arya. I was not really interested in politics or lobbying, so when I heard about the opportunity, I easily dismissed it. To be honest, I did not even know what to expect from the trip, because the event was not advertised too well. But now that I have been there, my opinions have changed and I hope that my reflection will interest and influence more students to participate in next year's event.

Several speakers, most of them presidents of various NYS pharmacy organizations, gave us inspiring opening statements—something that I did not anticipate so early in the day. The speakers mentioned how it is up to us, the students, to promote our profession and to lobby for a much-needed progress in pharmacy in New York.

Many pharmacists become complacent after getting a job. This attitude is fine for some people, but it will never move our profession forward. The majority of pharmacists I have worked with are not involved

in any pharmacy organizations, but I do not want to become one of them. I have already dedicated a large portion of my life to becoming a pharmacist, and I want to make a difference to get what is best for pharmacists as well as the patient population. It was inspiring to hear some of the sixth year students passionately lobbying for this year's two main talking points: expanding immunization rights for pharmacists and pharmacy interns, and CDTM. After the opening statements, students and faculty separated into small groups to talk to different assemblymen. Although not everyone was receptive, the majority of them were open to hearing us out. The high point of the event was when we spoke to a state senator who was very enthusiastic about expanding our immunization abilities.

On the other hand, CDTM was not accepted as easily, probably due to the misconception that CDTM gives pharmacists the ability to change doctors' orders on a whim without a proper understanding of disease states. The senator was more receptive to the idea after we clarified that the pharmacists will be consulting pre-established guidelines based on clinical research, just as physicians do. Based on what I saw, CDTM will probably require more lobbying and support before New York adopts it.

I was unaware and indifferent to issues pertaining to policy-making in pharmacy before going to Albany for this event. I was embarrassed to learn that New York is one of the last states to disallow pharmacists to carry out expanded immunization and CDTM. Even though New York is seen as progressive, the state's pharmacists are extremely restricted in their capacity to improve patient health.

Still, it was amazing to see that we could make a difference. These assemblymen and senators, who are all extremely busy, took the time to hear us out. This may be a stepping stone for our ideas come to fruition. Now I see the bigger healthcare picture that includes policy-making and implementation. Lobbying and talking to legislators determines the future of pharmacy. Despite my initial hesitation in attending this event, the experience was eye-opening and enjoyable. I plan on attending the next Pharmacy Day in a year, and I hope you will join me too.

PILLTALK: INNOVATION TO SIMPLIFY PATIENT COUNSELING

BY: MITESH PATEL, PHARM.D CANDIDATE C/O 2014



\$1.2 trillion- This is what the United States spends on healthcare. At 17% of GDP, this sector accounts for more spending in the U.S. than education, defense, welfare, and pension.¹ By 2016, our expenditure on healthcare will rise to \$1.6 trillion.¹ As our health care spending increases, Americans experience higher rates of disease, reduced access to health care, and fewer options for treatment.² According to the Health Reform Office, high disease rates are largely caused by the lack of access to health care and poor communication with health care providers (HCPs). Lack of education regarding medication and the importance of adherence leads to complications including re-hospitalizations.²

Management of any illness is most effective when a patient is educated about the disease. Effective patient counseling adequately informs patients and helps them understand their illness. It also enables them to make essential changes in their lifestyle to significantly improve overall health. Primary care providers and facilities that provide regular care to patients can enhance overall health. However, medication counseling from these professionals, pharmacists and pharmacy interns, can retard disease progression and reduce re-hospitalizations. Recent research suggests that professional counseling on medication can lead to safer medication usage, better adherence, and, ultimately, slowed disease progression.³

Despite heavy advocacy for improved patient counseling, it is neither as often nor as effective as need be. A National Community Pharmacy Association survey showed that 3 out of every 4 Americans

reported not taking their medications as prescribed.⁴ This poor adherence costs Americans about \$177 billion annually. Thus, adherence is a key determinant of patient outcome.⁴ Effective patient medication counseling could greatly reduce non-adherence and improve patient outcomes.

Effective patient counseling starts with a relationship between the patient and the provider. Today, HCPs are expected to compete more with fewer resources. Unfortunately, patient counseling in a busy environment may not be held as a priority given competing business objectives. Mobile applications such as PillTalk aim to address the need for improved patient counseling. PillTalk provides HCPs with a quick and easy-to-use reference tool simplify the counseling process. PillTalk, which was developed by St. John's alum Ryan Kuriakose and current student Ashlyn Jose, provides quick and effective medication counseling points such as administration, interactions, and side effects in a language simple enough to be recited to patients. "Although the app has just been released, we have received a lot of great feedback. Ryan and I hope that one day PillTalk will be embraced by healthcare providers as the go-to counseling app," says co-developer Ashlyn. HCPs always learn from their experiences with patients, and, after a while, they adapt their therapies and provide different counseling points based on their observations.

PillTalk provides HCPs a growing, organic platform to share those experiences, provide feedback on the effectiveness of therapies, and suggest counseling points that will benefit patients. This app is more than a reference tool—it fills a void in patient care. PillTalk does more than helping healthcare providers counsel patients. It enables healthcare providers to re-cultivate the relationships they have with their patients to improve the overall patient health.


SOURCES:

1. U.S. Government Spending Web site. Available at: http://www.usgovernmentspending.com/health_care_chart_10.html. Accessed February 7, 2012

2. Health Reform Government Web site, Available at: <http://www.healthreform.gov/reports/healthdisparities/>. Accessed on February 7, 2012
3. Khan I N, Patient counseling by pharmacist – A focus on chronic illness (Review). Available at: <http://www.pjps.pk/cd-pjps-19-1-06/paper-14.pdf>. Accessed on February 8, 2012
4. National Council on Patient Information and Education. Enhancing prescription medicine adherence: A national action plan. Available at: http://www.talkaboutrx.org/documents/enhancing_prescription_medicine_adherence.pdf. Accessed on February 7, 2012.

QUOTE OF THE MONTH

BY: ALEENA CHERIAN, CO-COPY EDITOR [GRAPHICS-FOCUSED]



To accomplish great things,
we must not only act,
but also dream. Not only plan,
but also believe.

-Anatole France

Rho Chi Post

Inspirational Words

ALZHEIMER'S DISEASE ON THE RISE

BY: ADA SELDIN, STAFF EDITOR

CLINICAL

An impending storm is threatening to stagger the health care system and the nation at large. Alzheimer's disease, which now affects as many as 5.1 million Americans, is projected to triple its toll by 2050, to 13.8 million Americans.¹ These sky-rocketing rates can be attributed to aging of the 'baby boomers.'² The prevalence of Alzheimer's disease doubles for every five years after age of 65.³ 'Baby boomers' refers to the 76.4 million people born in the United States between 1946 and 1964.⁴ People at the lower end of this group have recently turned 65, and thus their chances of developing Alzheimer's disease will exponentially increase in the coming years. Those at the upper end of the baby boomer range will turn 65 in about 15 years, and their prevalence of Alzheimer's will increase thereafter. These projections are significant, as a rise of this magnitude in the Alzheimer's disease population has the potential to drain healthcare resources and devastate both the victims of the disease and their caregivers.

Alzheimer's disease is a progressive neurodegenerative disorder involving neurons in the nucleus basalis that project throughout the cerebral cortex to the areas of the brain responsible for memory and cognition. The death of these neurons leads to memory loss, cognitive decline, behavioral and psychiatric disorders, and an increasing inability to perform daily activities. Alzheimer's patients often suffer from language disturbances such as anomic aphasia, a severe difficulty in recalling words or names. They also exhibit apraxia, the inability to perform a learned movement in response to a command, even though the command is understood, the patient is willing to obey, and the muscles needed for the movement are intact.

Perhaps most disturbing to caregivers and family members is the appearance of delusions, paranoia, and loss of social control. Deteriorating memory may present itself as the patient getting lost coming home from a place he or she frequents, such as the grocery store. The onset of the disease is insidious, and caregivers often cannot pinpoint when symptoms began to surface. In the late stages, Alzheimer's patients fail to recognize even their immediate family members.

Unfortunately, we have yet to develop a cure or treatment for this awful disease.

Current first line medications, the acetylcholinesterase inhibitors—donepezil, rivastigmine, and galantamine, temporarily slow the progression of the disease, but the patient ultimately continues to decline in mental, functional, and psychiatric status. Acetylcholinesterase inhibitors are most effective in the early stages of the disease. Later on, another drug called memantine could be added on to the existing therapy. However, memantine, too, shows marginal benefit.⁵ Thus, without truly effective medications, families are left to watch their loved ones wither away into a semblance of who they once were.

Alzheimer's has a tremendous impact on family members who act as informal caregivers. One can imagine how physically draining it is to care for a person who is disoriented and incapable of performing basic tasks, such as bathing and dressing. In addition, there is a significant emotional aspect to this disease as the caregiver observes his or her spouse, parent, grandparent, or sibling become helpless and sometimes psychiatrically unstable. As a result, caregivers have poorer overall health outcomes than their counterparts who do not provide such care. They often develop depression and anxiety, due to prolonged stress. Alzheimer's also inflicts a financial burden to both families and society. The yearly cost for a patient under 24-hour care at a nursing home is estimated at \$78,000.³ Nearly half of the nursing home population consists of residents with Alzheimer's disease. Moreover, people with Alzheimer's are hospitalized 2 to 3 times as often those without. The government absorbs a substantial amount of this financial burden through Medicare and Medicaid.³ Thus, it is in the financial and humanitarian interest of the government to find an effective means of preventing or curing Alzheimer's before it ravages the baby boomer population.

Recognizing the importance of finding a solution to the Alzheimer's crisis, the Obama Administration, on January 4, 2011, signed into law the National Alzheimer's Project Act (NAPA), which stipulates the formation of the Advisory Council on Alzheimer's Re-

search, Care, and Services. It also requires the Secretary of the U.S Department of Health and Human Services to establish the National Alzheimer's Project in collaboration with this council. The purpose of the National Alzheimer's project is "to create and maintain a national plan to overcome Alzheimer's disease." In February 2012, the Obama Administration took another leap in the fight against Alzheimer's when it announced a \$156-million investment to help meet the goals of the National Alzheimer's Project.³

The National Alzheimer's Project has set, as its foundation, five primary goals: to prevent and effectively treat Alzheimer's disease by 2025, to enhance care quality and efficiency, to expand support for people with Alzheimer's disease and their families, to enhance public awareness and engagement, and to improve data to track progress. Preventing Alzheimer's disease will require a better understanding of its underlying factors, in order to modify risk factors and promote protective factors.³ Although we have a vague understanding of the pathophysiology of the disease, the precise cause continues to elude us.

Early-onset Alzheimer's disease, which occurs in people ages 30 to 60 and comprises less than 5% of the total Alzheimer's population, has been linked to single gene mutations on chromosomes 21, 14, and 1. In each of these mutations, the abnormal breakdown of amyloid precursor protein is a primary cause of neuronal damage. This protein normally undergoes specific cleavage by the enzyme secretase before being broken down by the cell's proteasome. When the amyloid precursor protein is not properly cleaved, it cannot be broken down by the proteasome. Thus, it accumulates in the cell, leading to neuronal destruction and amyloid plaque formation. As more neurons die, the brain slowly atrophies, the characteristic signs and symptoms of Alzheimer's disease become apparent. On the other hand, a direct genetic association has not yet been found with late-onset Alzheimer's disease, which occurs in people over 60 and comprises the vast majority of cases.

Having a specific allele of apolipoprotein E predisposes one to developing Alzheimer's.⁶ The NIH is conducting whole genome sequencing to identify areas of genetic variation that correspond to increased

or decreased risk of developing the disease. This research is expected to yield new targets for drug development, to improve diagnostic screening and disease monitoring procedures, and, hopefully, to discover ways to prevent disease onset. The search for effective drug therapies will also involve bridging the gaps in our comprehension of the molecular and cellular mechanisms of Alzheimer's disease progression and conducting clinical trials on the most promising agents. HHS and the Department of Veterans Affairs continue to conduct clinical trials on both pharmaceuticals and lifestyle interventions. Because insufficient enrollment in such trials is a major barrier, HHS is also responsible for coordinating community-, national-, and international outreach programs to increase enrollment. The National Alzheimer's Project also seeks to coordinate federal government research with that of the private sector, as well as ongoing research abroad.³

The time frame set by the National Alzheimer's Project is consistent with the need to halt this disease in its tracks before the elderly population increases exponentially. As recognized and addressed in the NAPA, it is vital to promote Alzheimer's awareness and to educate the public about the disease. Although over 85% of Americans are aware of Alzheimer's disease, misconceptions about diagnosis and clinical management abound. These misconceptions can cause delays in diagnosis, which, in turn, reduce the effectiveness of treatment. Furthermore, widespread education can help Alzheimer's patients and their families feel less isolated and stigmatized.³ Perhaps most important, as Alzheimer's receives greater attention, the resulting increase in research initiatives and funding could bring us closer to a cure.

SOURCES:

1. "Alzheimer's Patient Population Projected to Triple by 2050." *Alzheimer's Patient Population Projected to Triple by 2050*. N.p., n.d. Web. 25 Mar. 2013.
2. "Alzheimer Disease in the United States (2010–2050) Estimated Using the 2010 Census." *Alzheimer Disease in the United States (2010–2050) Estimated Using the 2010 Census*. N.p., n.d. Web. 25 Mar.

2013.

3. "National Plan to Address Alzheimer's Disease." *National Plan to Address Alzheimer's Disease*. N.p., n.d. Web. 25 Mar. 2013.

4. "Baby Boomers." *History.com*. A&E Television Networks, n.d. Web. 25 Mar. 2013.

5. Beizer, Judith. "Alzheimer's Disease and Related Dementias," PowerPoint presentation. St John's University, D'Angelo Center Room 206, 3/12/13

6. "Alzheimer's Disease Genetics Fact Sheet." *National Institute on Aging*. N.p., n.d. Web. 25 Mar. 2013.

CAN A PHARMACIST PREVENT THE NEXT PILE-UP?

BY: MOISEY RAFAILOV, PHARMD CANDIDATE C/O 2015

It was early in the morning on New York's Route 684 when a car hit a tractor-trailer and continued driving without regard. Imagine that, when later stopped by a police officer, the driver said that the accident was her pharmacist's fault. What if I were to tell you that that she might have a point?

Kerry Kennedy, the daughter of former President John F. Kennedy, was taken to the hospital for this accident last July. Although she did not blame her pharmacist, her prescription sleep medication might have played a role in causing the collision. After the necessary blood tests, the only thing that was found was 14 nanograms of Zolpidem (Ambien®) per mL of blood, which equates to less than 0.1 mg systemically. Though physicians suggest that she might have had a seizure, Zolpidem might have played a role in what occurred that morning.¹

On January 10th 2013 the FDA made a drug safety announcement regarding this very matter. In summary, the FDA "recommends that the bedtime dose [of Zolpidem] be lowered because new data show that blood levels in some patients may be high enough the morning after use to impair activities that require alertness, including driving."² In fact, next morning impairment is possible with all sleep aids, especially extended release formulations.

The FDA suggests that the dose for women should be lowered from 10 mg to 5 mg for immediate release and from 12.5 mg to 6.25 mg for extended release products. Men, however, can use either strength, but are still urged to use the lowest dose possible. Furthermore, the FDA encourages all

healthcare professionals to inform their patients of possible next morning impairment, which may affect patients even when they feel fully awake.²

The purview of a pharmacist's influence is amazing - with one counseling session, a pharmacist could head off a car accident. Without one, pharmacists may well find themselves liable for situations like Ms. Kennedy's. It is safe to say that Ms. Kennedy's situation is not an isolated incident. Broadly speaking, there might be many people unaware of the most common side effects of medications they are taking.

Pharmacists are more than machines that fill, count, and dispense medications. A pharmacist can save others from discomfort, drug interactions, non-adherence, and potentially lethal outcomes.

SOURCES:

1. James, Susan Donaldson. "Kerry Kennedy and Ambien: A Common Med Mix (Up), Say Experts." ABC News. ABC News Network, 26 July 2012. Web. 28 Jan. 2013.
2. "Drugs." FDA Drug Safety Communication: Risk of Next-morning Impairment after Use of Insomnia Drugs; FDA Requires Lower Recommended Doses for Certain Drugs Containing Zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist). N.p., n.d. Web. 28 Jan. 2013.

PURPLE GLOVE SYNDROME

BY: SHARON JANAK, PHARM.D

How can we distinguish between vascular injury and Purple Glove Syndrome (an adverse effect of phenytoin)? What are the warning signs and symptoms?

Phenytoin is an anticonvulsant used to treat generalized tonic-clonic and partial seizures. It stabilizes neuronal cell membranes of the motor cortex by facilitating the efflux or inhibiting the influx of sodium ions when an electrical impulse is initiated. When phenytoin is injected into smaller veins in the hands, it can lead to Purple Glove Syndrome (PGS), a delayed soft tissue injury.^{2,3,4} Although PGS is often overlooked, the true prevalence of PGS may be as high as 5.9%.⁴

It is important to distinguish between PGS and other possible complications, such as extravasation and cellulitis. Several signs and symptoms can be used to differentiate between PGS and extravasation. If the patient is experiencing PGS, the symptoms such as skin discoloration, pain, and edema will continue to worsen despite discontinuing the phenytoin infusion and removing the catheter. The pattern and change of color are also distinct—the skin will turn from red to purple. During the progression stage of PGS, the discoloration spreads around the sides of the fingers, the hand, and the forearm. Petechiae, i.e. pinpoint, round, red spots, also occur due to intradermal hemorrhage. It is distinguished from cellulitis by its quicker onset, distinct discoloration, and lack of infectious discharge and fever.³

Patients experience edema, purple-blue discoloration, and pain in the hand and surrounding areas adjacent to the site of phenytoin administration. PGS progression has three stages: appearance, progression, and resolution. In the appearance stage, there is a bluish purple discoloration around the intravenous insertion site. However, it is important to note that the discoloration can start out as mild redness. This usually occurs 2 to 12 hours after phenytoin is administered. In the progression stage, edema, discoloration, and pain worsen as more tissue is damaged. The effects depend upon the dose and the

frequency of phenytoin administration. Patients may also experience fluid-filled blisters and sloughing of the skin.^{2,3,4} Upon closer inspection, petechiae on the finger pads and palms can be observed.³ During the resolution stage, the lesions, edema, and discoloration attenuate.^{2,3,4} Healing begins from the outer edges of the discolored area and gradually moves inward toward the site of venipuncture.^{2,3} The resolution stage generally takes about 2 to 4 weeks, but the pain may continue for weeks to months.³

There are several suggested mechanisms for the pathophysiology of PGS. One such mechanism is that the basicity of the intravenous phenytoin solution injures blood vessels. The high pH may lead to vasoconstriction, decrease blood flow, disrupt the endothelium, and leak phenytoin into the surrounding tissues. Since phenytoin is highly protein bound, oncotic pressure is increased outside the blood vessels, causing edema. Another possible mechanism is that the blood vessels are damaged by the insertion of an intravenous catheter. The small tears that occur help phenytoin leak into tissues. Other investigators have suggested that phenytoin solution mixes with precipitates from blood in the intravenous cannula, causing backflow and entry into the tissue. The final proposed mechanism is vasculitis, or inflammation of the blood vessels, which facilitates the formation of thrombi (blood clots impeding blood flow).^{2,4}

PGS can be prevented or recognized earlier in the course of progression. Risk factors for PGS include pre-existing vascular disease, unconsciousness (rendering the patient unable to report pain), female gender, age over 60 years, and age below 7 years.^{2,3,4} These populations should be assessed more frequently to prevent any complications. To prevent vessel injury, Snelson and Dieckman recommend a maximum infusion rate of 40 mg/min for most patients. Cardiac patients should receive phenytoin at a rate no greater than 25 mg/min, preferably between 5 and 10 mg/min. A large vein in the forearm should be used, as opposed to a smaller one on the dorsal side of the hand.³ A catheter larger than 20 gauge⁷ and a 0.22-micron filter should

also be used.³ The area around the site of infusion should be carefully and regularly examined. If any abnormalities develop, the intravenous catheter should be removed.³

To treat PGS, the phenytoin infusion should be discontinued, and the patient should be given supportive care. Examples of such care include frequently assessing the affected area, applying dry heat and a compression glove or splint, and elevating the limb. This will help mitigate symptoms and aid in healing.^{2,3,4} Many cases have been managed successfully with complete resolution of symptoms after one month.^{5,6,7} In rare cases, PGS can be severe enough to warrant surgery or amputation.⁵

Purple Glove Syndrome is a relatively rare and often overlooked adverse effect of phenytoin administration. The serious risks associated with the syndrome warrant more proactive care such as monitoring higher-risk patients. By successfully identifying PGS early, and not confusing it with other problems such as extravasation and cellulitis, patients can be treated sooner and faster, saving them from months of painful reactions.

SOURCES:

1. Phenytoin. Lexi-Comp Online. Hudson, OH. Available at: <http://online.lexi.com/crlonline>
2. Bhattacharjee P, Glusac E. Early histopathologic changes in purple glove syndrome. *Journal of Cutaneous Pathology*. 2004; 31: 513–515.
3. Snelson C, Dieckman B. Recognizing and Managing Purple Glove Syndrome. *Critical Care Nurse*. 2000; 20:3; 54 – 61.
4. Chokshi R, Openshaw J, Mehta NN, Mohler E. Purple glove syndrome following intravenous phenytoin administration. *Vascular Medicine*. 2007; 12: 29–31.
5. O'Brien TJ, Cascino GD, So E, Hanna DR. Incidence and clinical consequences of the purple glove syndrome in patients receiving intravenous phenytoin. *Neurology*. 1998; 51:1034-1039.
6. Sonohata M, Asami A, Tsunodal K, Hotokebuchi T. Purple glove syndrome associated with intravenous phenytoin administration in a patient with severe mental and motor retardation. *Journal of Orthopaedic Science*. 2006. 11:409–411.
7. Santoshi JA, Justin AS, Jacob JI, Pallapati SC, Thomas BP. Purple glove syndrome: a case report: Hand surgeons and physicians be aware. *Journal of Plastic, Reconstructive & Aesthetic Surgery*. 2010. 63: e340-2.

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DISCLOSURE OF CLINICAL RESEARCH FUNDING: CAN IGNORANCE BE BLISS?

BY: BHARAT KIRTHIVASAN, CO-COPY EDITOR [CONTENT-FOCUSED]

Most people would prefer that a research paper be mandated to disclose its source of funds. For example, if a publication effusively supports a certain drug, we want to know if its parent company is footing the bill. Transparency allows research to be viewed in light of its inherent biases and brooks an objective examination of its conclusions.

Or does it? What about *our* biases? I have never read a research paper without noting the authors' names, affiliations, and funding sources, and these details affect my first impression of the research. Knowing that a paper comes from a prestigious university or that it's published in a high-impact journal makes us less skeptical—our burden is shared by the editors and peer-reviewers of said journal. Simply put, they wouldn't publish it if it weren't good.

But this does not allow for high-quality research and analysis. The veracity of an experimental conclusion is independent of who the scientists are and who funds them. It is human nature to shudder at the thought of a pharmaceutical company nudging its research toward a favorable conclusion, and it is likely that people get hurt as a result of such flaws in studies. But a blanket distrust of research that is funded by pharmaceutical industries stands to harm more people.

While such prejudice would be expected of the general public, physicians aren't immune to it either. Kesselheim *et al.* (2012) asked board-certified internists to judge the abstracts of clinical trials involving three fictitious drugs.^{1,2} The internists were randomly told that the trial in question was of low, medium, or high methodological rigor. Each trial report also included one of three disclosures of financial support: a pharmaceutical company, the National Institutes of Health (NIH), or none. About 54% of the surveyed physicians responded, and the results indicated that their willingness to prescribe a drug increased with the methodological rigor of the study. Furthermore, the physicians were half as likely to prescribe a drug if a pharmaceutical company, as opposed to the NIH, was purported to have funded the research. In fact, the knowledge that a trial was industry-funded adversely affected the internists'

opinion of its methodological rigor. The authors concluded:

"Physicians discriminate among trials of varying degrees of rigor, but industry sponsorship negatively influences their perception of methodologic quality and reduces their willingness to believe and act on trial findings, independently of the trial's quality."^{1,2}

To be fair, a pharmaceutical industry does stand to gain from research favoring its product. In fact, Lexchin *et al.* (2003) reported that an industry-funded article was about four times more likely to favor its sponsor than an article with other sponsors.³ Als-Nielsen *et al.* (2003) reported similar odds.⁴ There are two reasons for such a skew in studies conducted honestly: (1) biased interpretation of experimental results and (2) publication bias—studies showing positive results are more likely to be published. Either way, the skepticism of industry-sponsored research isn't unfounded.

"...the knowledge that a trial was industry-funded adversely affected the internists' opinion of its methodological rigor."

Nor is it inappropriate, say Dr. Keyhani and Dr. Korenstein.⁵ In a perfect world, clinicians would pore over methodologies and appraise clinical trials accurately. In reality, most clinicians only read the abstracts.⁶ Also, physicians without training in the methodology of clinical trials would find it difficult to identify errors of method and judgment that escaped peer-review.

The total spending on clinical trials of investigational drugs and devices in the U.S. reached \$35 billion in 2008, of which industry funding accounted for nearly \$32 billion (90%).⁷ A physician's opinion of industry-funded clinical research, flawed or otherwise, has a lot of influence. Dr. Kesselheim explains,

"While there is good reason to be extra vigilant about industry-funded research, if physicians are reluctant to trust all such research, this could hinder the translation of even high-quality industry-funded re-

search into practice. Strategies such as greater transparency and independent review of trial data could be pursued to try to change such attitudes among physicians”^{1,2}

SOURCES:

1. Kesselheim AS et al. A randomized study of how physicians interpret research funding disclosures. *N Engl J Med*. 2012; 367(12):1119-27
2. Can disclosure hurt the translation of research? World Pharma News. 2012. Available at <http://www.worldpharmanews.com/research/2212-can-disclosure-hurt-the-translation-of-research>. Accessed March 10, 2013.
3. Lexchin J et al. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ* 2003;326:1167

4. Als-Nielsen B et al. Association of funding and conclusions in randomized drug trials: a reflection of treatment effect or adverse events? *JAMA*. 2003; 290(7):921-8

5. Keyhani S. and Korenstein D. Physician skepticism about industry-funded clinical trials. The Medical Professionalism Blog, ABIM Foundation. 2012. Available at <http://blog.abimfoundation.org/physician-skepticism-about-industry-funded-clinical-trials/>. Accessed March 10, 2013

6. Hopewell S, Eisinga A, and Clarke M. Better reporting of randomized trials in biomedical journal and conference abstracts. *J Inf Sci*. 2008; 34(2). 162-173

7. Getz. KA. Sizing up the clinical research market. *Applied Clinical Trials Online*. 2010. Available at <http://www.appliedclinicaltrialsonline.com/>

REGULATION OF LOW TO MODERATE RISK MEDICAL DEVICES BY THE FDA

BY: HAYEON NA, CO-COPY EDITOR [CONTENT-FOCUSED]

On 22 March 2013, Public Broadcasting Service (PBS) aired an episode of “Need to Know” on the safety of low to moderate risk medical devices. The episode closely followed the lawsuit of patient Linda Gross who has pelvic organ prolapse and was advised by her doctor to undergo a minimally invasive procedure that places a mesh implant called Prolift® in her pelvic area. Gynecare Prolift® is made by Ethicon, a subsidiary of Johnson and Johnson. Before the implant surgery, Gross was told that the mesh could be removed if there were immune rejections; however, she later found out that this was not the case.

Gross had Prolift® implanted in July of 2006.¹ The surgery was successful, but she suffered from incessant sharp pains that disabled her from carrying out simple tasks. “Need to Know” informs that Gross decided to have the mesh removed 5 months later, but the doctor was unable to remove the whole mesh because her tissues had already grown into the device. She had multiple surgeries in which parts of the mesh were “cut out like bubblegum in your hair.”⁷ In total, Gross had 22 surgeries that involved Prolift®. She is no longer able to have sexual intercourse with her husband Jeff Gross, and suffers from pain that can only be controlled with narcotic pain medication.⁷

Linda and Jeff Gross attempted to contact Ethicon but did not receive a response. The Grosses hired attorney Adam Slater who sued Ethicon and Johnson and Johnson on their “failure to warn” consumers. Linda Gross was awarded \$11.1million—\$7.76 million in punitive damage and \$3.35 million in compensatory damage—on February 25, 2013. In response, Ethicon issued a statement that it would appeal the verdict. There are thousands of other cases brought against Ethicon and other transvaginal mesh manufacturers, and “Need to Know” questioned whether the Food and Drug administration (FDA) approval process for low-to-moderate risk medical devices was adequate to ensure the safety of consumers, and whether the process was even being followed.

Prolift® was introduced in 2005 without being cleared by the FDA. Ethicon’s Prolift® website states that over 120,000 women have received Prolift® implantations since 2005, when the device was marketed without FDA clearance. According to *Bloomberg*, the FDA warned Johnson and Johnson that the device had a “potential high risk for organ perforation” in August 2007.²

"You may not market this device until you have provided adequate information," ...the agency told the New Jersey-based company... "If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug and Cosmetic Act." ²

The FDA published an adverse event report on May 1st, 2008 that stated that a patient's Prolift® "crumpling into a ball" inside her body and caused her to have "jabbing pains" which led to a hysterectomy two months later. The result of this case report was "inconclusive"³ and Prolift®'s sale was not suspended. On the contrary, Prolift® was approved on May 15, 2008 on the grounds of being substantially equivalent to Gynemesh®, a product which was approved in 2004.⁴ In June 2012, Johnson and Johnson discontinued Prolift® for profit reasons after lawsuits were filed against the product.⁶

In August 2010, "Vaginal Mesh for Prolapse: A Randomized Controlled Trial Study" by Iglesia, et al. was published in *Obstetrics & Gynecology*. The study was conducted for 3 months and involved 65 women who had organ prolapse. The conclusion of the study was that the difference in "objective and subjective cure rates" between the group that had Prolift® and the group that did not was insignificant, but the mesh group had a higher rate of complications such as "vaginal mesh erosion."⁵

"...The experts concluded that the process was 'flawed' and recommended that the FDA come up with an entirely 'new framework.'"

Some medical devices and medications pose a challenge when it comes to clinical trials, which makes it difficult to determine the safety and efficacy. Gregory Curfman, the executive editor of the New England Journal of Medicine, says that the current clearance process of proving "substantial equivalence" to an existing device that is marketed "does nothing to ensure the safety and the effectiveness of the device."⁷ He believes that a more thorough review process of medical devices is needed.

David Nexon, the Senior Executive Vice President of Advamed—a trade association that represents medical device manufacturers—says that the process in place allows "innova[tion] much more rapidly."⁷ However, problems arise when the old, prov-

en devices are recalled after generations of new devices are approved by proving substantial equivalence. Much like how the Jenga™ tower fall when the lower blocks are removed, when too many of the older devices are recalled, the safety of newer devices that were approved upon the older devices is brought into question.

"For instance, Johnson and Johnson's pelvic mesh traces its lineage back to various mesh products dating back decades. But one of those products was recalled in 1999." After reports of injuries, Curfman says examples like this show why a more thorough review process of medical devices is needed. ⁷ (p4)

It takes more time and capital to bring innovation into play when every new device has to be built from the ground up; however, it is also impossible to ensure the safety of a device without thorough review involving clinical trials. This poses a burden on the manufacturers to invest millions of dollars in research and development, which may suppress competition.

"...Current clearance process of proving 'substantial equivalence' to an existing device that is marketed 'does nothing to ensure the safety and the effectiveness of the device.' He believes that a more thorough review process of medical devices is needed."

The FDA commissioned a report from independent medical experts about its clearance process for low to moderate risk devices [in July 2011]. The experts concluded that the process was 'flawed' and recommended that the FDA come up with an entirely 'new framework.' Despite the findings, the FDA later issued a response [that the] clearance process should 'not be eliminated.'⁷ (p5)

Even though both safety and innovation are important in the making of new products, many consider that the two are at odds with each other. In the show, Host Jeff Greenfield asked Josh Rising, Project Director of the Medical Device Initiative at the Pew Charitable Trusts, how the United States compares to other countries in regards to medical device safety, and how post-market surveillance could be im-

proved. According to Rising, post-marketing surveillance is the answer to both fostering innovation and ensuring safety. In Australia, there has been a registry for the past 10-12 years that tracks Australians who has received hip or knee replacements. This enables a real-time update on adverse effects and thus a faster reaction by medical personnel. Due to this system, doctors in "Australia stopped using metal-on-metal hip replacements years before those in [the United States]." ⁷ (p7)

Rising also stated that medical devices need a unique ID to track the devices to not only to more efficiently alert manufacturers of a problem but also to inform consumers about a recall issued or an adverse effect discovered. Rising asserts that devices are "one of virtually the only consumer products that don't have a unique number." ⁷ (p8) Currently, only the clinicians are in charge of informing patients of a complication. Therefore, if the clinician retires, loses track of the patient, or passes away, he or she can no longer inform the consumers. Once in place, the unique device ID system would also benefit the manufacturers because they can collect data and use it to improve their next products.

In the US, Medwatch and NHRIC can be compared to a registry and unique ID number. Medwatch was founded in 1993 as FDA's adverse event reporting system concerning medical products. Reports are voluntary for the general public and health care professionals and mandatory for manufacturers, importers, and medical product user facilities that manage and store medical products.⁸ However, there is no registry that keeps track of individual patients who are using individual devices.

The FDA has set aside a set of numbers in the 1970s for National Health Related Items Code (NHRIC), a system for identification and numbering of marketed device packages.⁹ This is voluntary, and manufacturers who desire to use the NHRIC number for unique product identification may apply to FDA for a labeler code.¹⁰ The labeler code of Ethicon Inc. is 8135, assigned in February of 1970.¹¹ The NHRIC of Prolift® could not be easily located upon research.

In "Need to Know," NHRIC and Medwatch were not mentioned by Rising. If NHRIC was used judiciously, it may be useful in improving post-marketing surveillance. However, simply improving post-

marketing surveillance without stricter FDA requirements would make some consumers "test subjects" for low to moderate-risk devices. Both post-marketing surveillance, which keeps track of patients who use the device, and FDA regulation, which involves tightening the standards for new devices before they go on market, need to be reconsidered. This process is surely to involve patients, clinicians, the FDA, and the manufacturers.

More patients benefit from innovation as new devices come onto the market; at the same time, patients risk unknown adverse effects with newer medical products. When health professionals recommend new treatments, patients should not submit to "therapeutic misconception," or assume that the product is safe and efficacious. Instead, patients and clinicians should make medical procedures an active process by actively researching the products before use and by providing following-up services.

If all of these measures were implemented, there would surely be a decrease in the sale of defective products and the incidence of serious adverse effects, which would result in fewer lawsuits and less health resources lost on the repetitive litigations that involve medical products. After researching their options, more prudent consumers will demand the manufacturers design products that are safer and more efficacious, even without stricter FDA regulations. Since the need for stricter regulation for low to moderate risk medical devices will diminish, this will prevent the ballooning of government healthcare costs. Not only should there be no mistakes made by the FDA and the manufacturers, but the consumers and the clinicians should also scrutinize products beforehand to create more opportunities to catch mistakes.

"Along with a better use for NHRIC and Medwatch, working together in the health care system instead of pointing fingers will help achieve safer, more efficacious products at lower costs."

It is unfortunate that so many patients suffered from disabling adverse effects and my deepest condolences go out to those who suffer. Tragedy like this should not go on; this is an opportunity to involve everyone to better the health care system. Along

with a better use for NHRIC and Medwatch, having all parties informed, involved, and working together in the health care system instead of pointing fingers or blaming only one sector will help achieve what everybody desires—safer, more efficacious products at lower costs.

SOURCES:

1. Akre J. Day 14: Linda Gross v. Ethicon, Ms. Gross Takes the Stand. Mesh Medical Device Newsdesk. <http://meshmedicaldevicenewsdesk.com/latest-in-the-litigation-concerning-mesh-and-medical-devices/day-14-linda-gross-v-ethicon-she-takes-the-stand/>. Published January 31, 2013. Accessed March 22, 2013.
2. Voreacos D, Nussbaum A. J&J Sold Vaginal Mesh Implant After Sales Halt Ordered. Bloomberg. <http://www.bloomberg.com/news/2012-06-26/j-j-sold-vaginal-mesh-implant-after-sales-halt-ordered.html>. Published June 26, 2012. Accessed March 23, 2013.
3. U.S. Food and Drug Administration. MAUDE Adverse Event Report: ETHICON, INC. PROLIFT® PELVIC FLOOR REPAIR MESH, SURGICAL, POLYMERIC. U.S. Food and Drug Administration. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=1095383. Published May 1, 2008. Accessed March 23, 2013.
4. U.S. Food and Drug Administration. Summary of Safety and Effectiveness K071512. U.S. Food and Drug Administration Access Data. http://www.accessdata.fda.gov/cdrh_docs/pdf7/K071512.pdf. Published May 15, 2008. Accessed March 23, 2013.
5. Iglesia CB, Sokol AI, Sokol ER, et al. Vaginal mesh for prolapse: a randomized controlled trial. *Obstet Gynecol*. 2010;116: 293–303.
6. Drugwatch. Transvaginal Mesh Recall. Drugwatch. <http://www.drugwatch.com/transvaginal-mesh/recall.php>. Published Feb 27, 2013. Accessed March 23, 2013.
7. Public Broadcasting Service. Transcript: March 22, 2013. Public Broadcasting Service. <http://www.pbs.org/wnet/need-to-know/transcripts-full-episode/transcript-march-22-2013/16591/>. Published March 22, 2013. Accessed March 23, 2013.
8. Craigle V. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. *J Med Libr Assoc*. 2007 April; 95(2): 224–225.
9. U.S. Food and Drug Administration. Medical Devices. U.S. Food and Drug Administration. <http://www.fda.gov/medicaldevices/deviceregulationandguidance/databases/default.htm>. Published Mar 5, 2013. Accessed March 23, 2013.
10. U.S. Food and Drug Administration. More about National Health Related Items Code - NHRIC. U.S. Food and Drug Administration. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm161456.htm>. Published Aug 31, 2009. Accessed March 23, 2013.
11. U.S. Food and Drug Administration. NHRIC - National Health Related Items Code. U.S. Food and Drug Administration. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfNHRIC/nhric.cfm?ID=136>. Published Mar 1, 2013. Accessed March 23, 2013.

Went to an event on your campus?

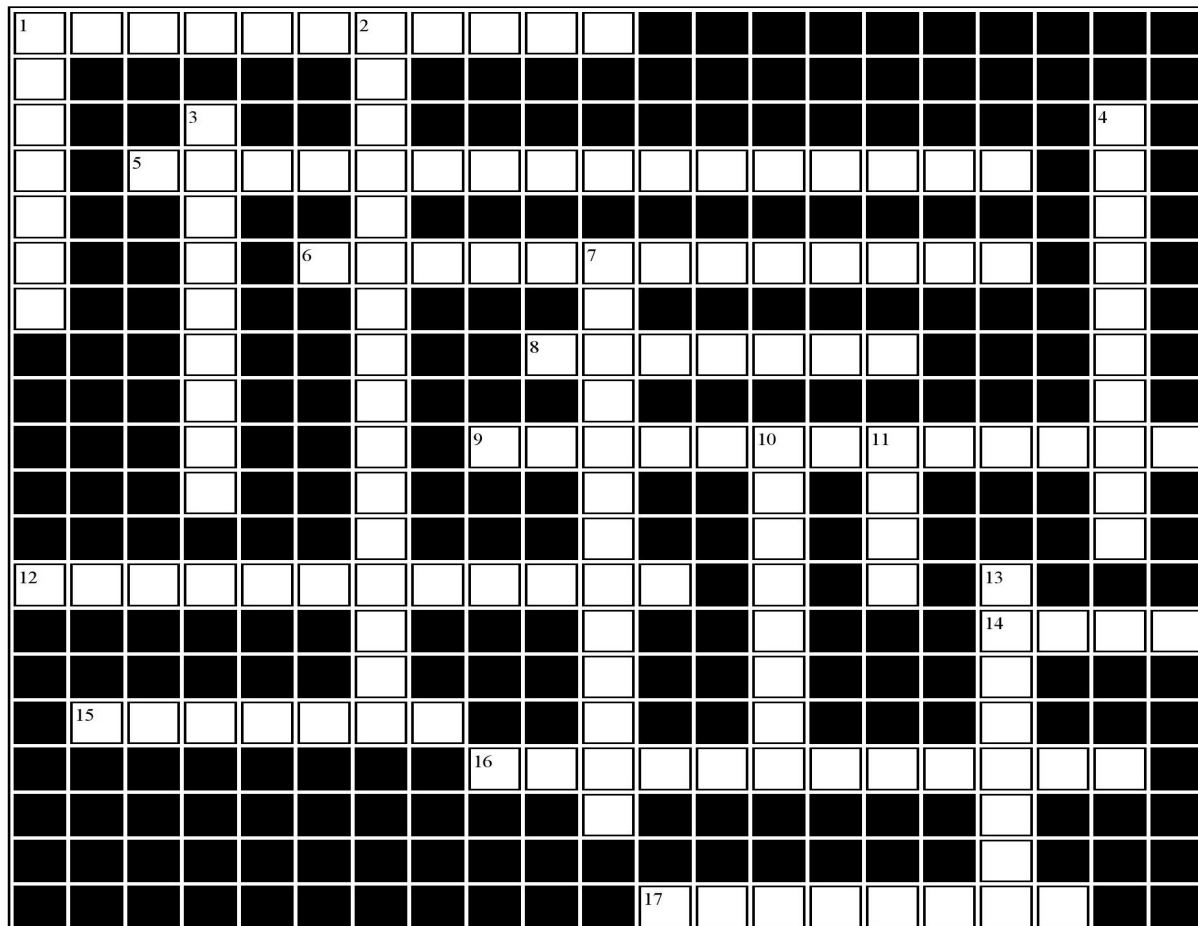
Learned something interesting?

Write to our editors at RhoChiPost@gmail.com

and we will feature your article in our next issue!

CROSSWORD PUZZLE: AGENTS OF TOXICITY AND TREATMENT

BY: MAHDEIH DANESH YAZDI, PHARM.D



Across

1. Mercury, Gold, Arsenic
5. Atropine and Pralidoxime
6. N-Acetylcysteine
8. Fomepizole, Methanol
9. Anticholinergic Agents
12. Warfarin
14. Edetate Calcium Disodium
15. Hydroxocobalamin
16. Methotrexate
17. Opioids

Down

1. Digibind, DigiFab
2. Tissue Plasminogen Activators
3. Heparin
4. Benzodiazepines
7. Methemoglobin
10. Lead
11. Deferoxamine
13. Beta Blockers



By: Frances Trosa,
PharmD Candidate 2015

Many drugs

LOOK – ALIKE

OR

SOUND– ALIKE

causing them to be easily
mixed up in practice.

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

Matching Column: Look-Alike Sound-Alikes

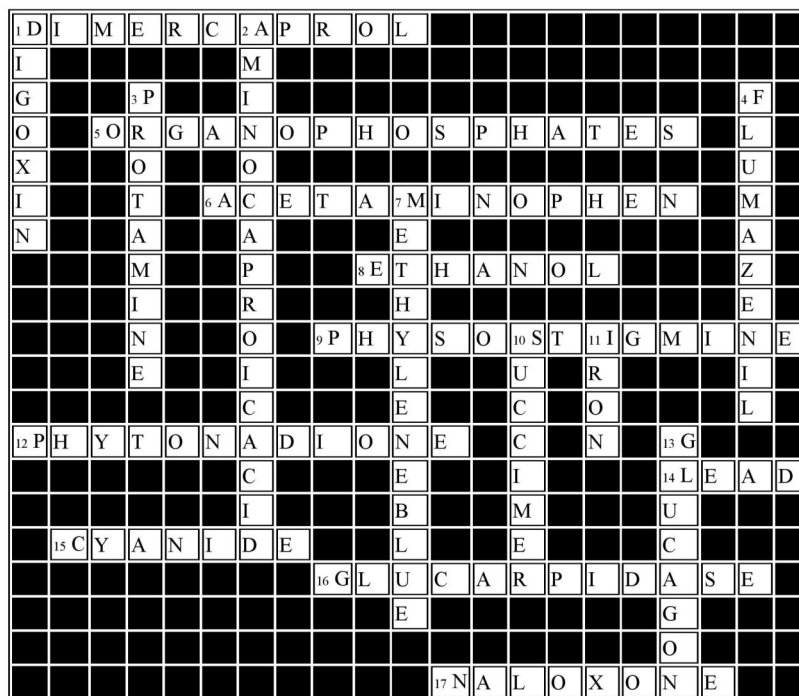
- | | |
|---|------------------|
| 1) This drug is used to treat gastroesophageal reflux disease and is best taken 30 minutes before the first meal of the day. | A) Acuvail |
| 2) One of several of the black box warnings of this drug is that all patients should be advised not to donate blood during therapy or for 3 years following completion of therapy. | B) Acitretin |
| 3) This drug is used to treat edema, epilepsy, altitude sickness, and glaucoma. | C) Acetazolamide |
| 4) Use with caution in hepatic impairment, this drug may cause severe hepatotoxicity on acute overdose. | D) Actos |
| 5) This drug has intrinsic sympathomimetic activity. | E) Actonel |
| 6) This drug has a black box warning, which states: Drugs that act on the rennin angiotensin system can cause injury and death to the developing fetus. Discontinue as soon as possible once pregnancy is detected. | F) Acebutolol |
| 7) After this drug is converted to the triphosphate form in vivo, it inhibits DNA synthesis and viral replication. | G) Acyclovir |
| 8) This drug can be used to treat Paget's disease of bone. | H) Accupril |
| 9) This drug reversibly inhibits COX 1 and 2 enzymes, which ultimately results in a decrease in formation of prostaglandins. | I) Aciphex |
| 10) This drug has a black box warning that it may cause or exacerbate heart failure and is therefore contraindicated for initiation in patients with NYHA class III or class IV heart failure. | J) Acetaminophen |

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

Graphic Design By: Melissa Roy, PharmD Candidate 2015

CROSSWORD PUZZLE SOLUTION

BY: MAHDEIH DANESH YAZDI, PHARM.D



Across

1. Mercury, Gold, Arsenic
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Do you enjoy our puzzles?

Send us a suggestion for a brainteaser at

rhochis@gmail.com

We will feature your work in our next issue!

RHO CHI POST: EDITORIAL TEAM



@ Katharine Cimmino (4th Year, STJ; Editor-in-Chief)

I have always been an avid reader and writer. As a member of the Rho Chi Post I am able to merge my passions with the professionalism that comes with aspiring to be a healthcare provider. I am eager to be a part of a publication that promotes my interests and vocation.



@ Bharat Kirthivasan (PhD Candidate, STJ; Co-Copy Editor [Content-Focused])

I am a doctoral candidate in Industrial Pharmacy researching nanoparticles for delivery to the brain. The only thing I enjoy more than reading a well-written piece of work is writing it. I am glad to work for the Rho Chi Post, and I encourage others to do the same.



@ Hayeon Na (4th Year, STJ; Co-Copy Editor [Content-Focused])

Hello! My name is Hayeon Na. I am a 2015 PharmD Candidate and one of the Copy Editors for the Rho Chi Post. I hope the information I present will be helpful, or at least interesting. If you have any comments regarding my contribution, feel free to contact me at any time!



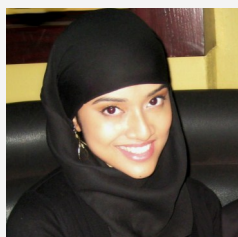
@ Aleena Cherian (5th Year, STJ; Co-Copy Editor [Graphics-Focused])

The Rho Chi Post has been a source of current information and great advice to students and professionals in this evolving profession. After years of experience in media and graphics-related work, it is now my privilege to be a part of this endeavor as a Co-Copy Editor. I hope you learn as much from future editions of the newsletter as I have, and I welcome your feedback!



@ Erica Dimitropoulos (4th Year, STJ; Senior Staff Editor)

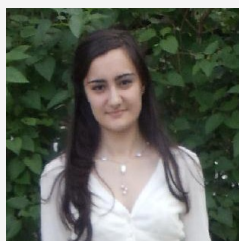
As busy student pharmacists, we often fail to keep current with healthcare developments. My aim is to sort through the news and provide quick updates that are important to our profession. Feel free to contact me if there are any topics you would like to see covered in the next issue!



@ Tasnima Nabi (3rd Year, STJ; Senior Staff Editor)

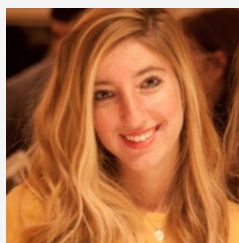
Writing has always been my greatest outlet for experience and knowledge, through which I hope to keep you engaged and informed. It is imperative to keep up with our changing profession and community, and I look forward to bringing pertinent information to the newsletter.

RHO CHI POST: EDITORIAL TEAM



@ Tamara Yunusova (2nd Year, STJ; Senior Staff Editor)

My name is Tamara Yunusova, and I am a 2nd year Pharm D candidate at St. John's University. I enjoy articulating information in a captivating and insightful way. I hope to make this publication more informative, student-friendly, and innovative.



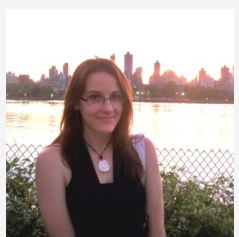
@ Beatrice Popovitz (4th Year, STJ; Staff Editor)

I am eager to relay current information on interesting topics making waves in the world of healthcare pertinent to the advancement of our profession. As student pharmacists, we are molding the future of our profession, and the Rho Chi Post facilitates the cultivation of a relationship (between students, faculty, and other members of the healthcare community) to share ideas and spread awareness of various issues. Feel free to contact me if you would like to share your ideas with other members of the University community through this platform.



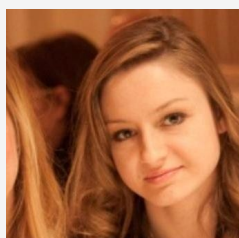
@ Omar Khalid (5th Year, STJ; Staff Editor)

I am honored to be a part of this great publication. Pharmacy is in a period of drastic change and growth as we move from behind the counter to on the floor interacting as pivotal members of a healthcare team. I wish to promote this growth and be at its forefront as I bring awareness to the great amount of benefit pharmacists can bring to society.



@ Diana Gritsenko (4th Year, STJ; Staff Editor)

I am proud to serve as an editor for the Rho Chi Post. The Post combines my love for Pharmacy and writing and I am glad to share that passion with all of you! I look forward to working with you and sharing this amazing opportunity!



@ Ada Seldin (4th Year, STJ; Staff Editor)

I am thrilled to have become a new member of the Rho Chi Post team. I hope to further strengthen the goals of this newsletter and make a lasting contribution. It is important, as future pharmacists, to collaborate with our peers, as well as accomplished professionals in the field. Rho Chi Post provides a vehicle to voice our opinions and share relevant news.



@ you!

We are always looking for creative and motivated students to join our team!

If you are interested in becoming an editor for the Rho Chi Post, please visit:
http://rhochistj.org/RhoChiPost/?page_id=36

RHO CHI

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

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

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

THE RHO CHI POST

MISSION

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

VISION

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

VALUES

Opportunity, Teamwork, Respect, Excellence

GOALS

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

CURRENT EXECUTIVE BOARD



Zinnia, Majd, Moisey, Elissa, and Anh at the 2013 Induction Ceremony

President: **Moisey Rafailov**
 Vice President: **Majd Ahmad**
 Secretary: **Elissa Tam**
 Treasurer: **Anh Nguyen**
 Historian: **Zinnia L. Yu**

Faculty Advisor: **S. William Zito, PhD**

UPCOMING EVENTS

May 6-8: Strategic Alliance Management Congress

Loews Hotel, Philadelphia, Pennsylvania,

May 8-10: Pharma Project Management Workshop

Holiday Inn Mumbai International Airport, Mumbai, India

May 16: Doctor of Pharmacy Hooding Ceremony

Carnesecca Arena, St. John's University, New York

May 16-19: International Stress and Behavior Neuroscience and Biopsychiatry Conference

Oktiabrskaya Hotel, St-Petersburg, Russia

May 19: University 2013 Commencement Ceremony

Great Lawn, St. John's University, New York

May 21-22: Optimizing Pre-Clinical Drug Safety Conference

Omni Parker House, Boston, Massachusetts

May 28-31: Molecular Medicine Tri-Conference by Cambridge Healthtech Institute (CHI)

Marina Bay Sands, Singapore