RHO RCHO VOLUME 2, ISSUE 9

WWW.RHOCHISTJ.ORG

- IN THE NEWS / POLITICS
- LOCAL EVENTS
- CLINICAL ARTICLES
- PROFESSIONAL ADVICE / OPINIONS
- PUZZLES
- CURRENT EDITORIAL TEAM

A STUDENT-OPERATED NEWSLETTER BY THE

ST. JOHN'S UNIVERSITY COLLEGE OF PHARMACY AND HEALTH SCIENCES' RHO CHI BETA DELTA CHAPTER

Inside This Issue

Lupus	1
Quote of the Month	2
OxyContin	3
Coffeehouse Chats	6
Coffeehouse Pictures	8
Cancer Screening	10
Multiple Sclerosis	12
Pay To Delay	14
Feature Interview	15
Crossword Puzzle	17
Look-Alike Sound-Alike	18
Crossword Puzzle Answers	19
Editorial Team Bios	20
Upcoming Events	22
About Us	22

Helping Solve the Cruel Mystery

By Erica Dimitropoulos, Senior Staff Editor

Lupus is highly unpredictable and occurs without warning; there is no known cause and no known cure. It affects over 1.5 million Americans, 90% of whom are women between the ages of 15 - 44.¹ No two cases of lupus are alike, making it a very difficult disease to understand and diagnose. A typical lupus "flare" can be characterized by any or all of the following: joint pain and swelling, muscle pain, fever, headache, extreme fatigue, chest pain, shortness of breath, nausea, vomiting, abdominal pain, and skin rashes such as a maculopapular rash (a characteristic "butterfly" rash on the face).² Although there is no cure for lupus, various treatment regimens exist to lessen symptoms and alleviate pain. For example, nonsteroidal anti-inflammatory drugs (NSAIDS) and corticosteroids are generally used to control flares, and immunosuppressive agents and antimalarials have been used for long-term therapy.²

On March 9, 2011, belimumab (Benlysta®) was named the first approved treatment for patients with active, autoantibody-positive lupus in over fifty years.² Scientifically, Systemic Lupus Erythematosus (SLE) is a multi-system autoimmune disease wherein one's immune system attacks its own otherwise healthy cells and tissues, causing damage and inflammation to joints, skin, and various organs throughout the body.³ Therefore, this relatively new drug was created to work against the large numbers of autoantibodies that are produced by over stimulated B cells, which otherwise bind to selfantigens and form immune complex depositions that cause inflammation and tissue damage throughout the body. Belimumab works specifically by binding to a protein called BLyS (B Lymphocyte Stimulator), thereby blocking its ability to bind and activate the potentially destructive autoreactive B cells.²

Continue Reading on Page 4....

Single Line Stories

- Did you know that we also publish during the summer months? -

- Follow us on Twitter @RhoChiPost and on Facebook: FB.com/RhoChiPost -



Quote of the Month

By: Aleena Cherian, Co-Copy Editor

Education without values, as useful as it is, seems rather to make man a more clever devil.

C. S. Lewis

Inspirational Words | Px | Rho Chi Post 2013



FDA Takes Major Strides Towards Opioid Abuse Prevention

By: Ada Seldin, Staff Editor

On April 16th, 2013, the FDA approved the labeling change for the reformulated OxyContin[®] (oxycodone hydrochloride controlled-release) tablets, made by Pharma L.P. This change reflects the abuse-deterrent properties of the reformulated OxyContin[®], which were not present in the original formulation approved by the FDA in 1995. OxyContin[®] is intended to be used around-the-clock over an extended period of time for the relief of moderate to severe pain. The tablets must be swallowed whole to ensure the slow release of the drug. Breaking, chewing, crushing, or dissolving OxyContin[®] tablets com-

"Breaking, chewing, crushing, or dissolving OxyContin® tablets compromises their medicinal purpose and safety profile"

promises their medicinal purpose and safety profile. However, OxyContin[®] is often manipulated to bypass its extended release features.¹ In this case, the rapid release and absorption of the drug can lead to overdose and death.²

In an attempt to reduce abuse and misuse, Purdue came out with the reformulated OxyContin[®], which received FDA approval in April 2010. The new formulation is more difficult to crush, break, or dissolve, and it forms a viscous hydrogel that prevents abusers from attempting to directly inject or insufflate the drug. These chemical and physical properties of the drug have shown to substantially reduce abuse, prompting the FDA to approve the claim on the product labeling.¹ This action is the first of its kind, consistent with the FDA's efforts to reduce prescription drug abuse, and may foreshadow a trend in the development of safety mechanisms for other commonly abused substances.³ The FDA released guidelines on the development of tamper-resistant characteristics for manufacturers in March and has offered its assistance in implementing them.⁴

In addition to this landmark approval, the FDA has determined that "the benefits of the original OxyContin[®] no longer outweigh its risks, and that original OxyContin[®] [will be] withdrawn from sale for reasons of safety and effectiveness."¹ Logically, the FDA will no longer accept abbreviated drug applications that are based on the original OxyContin[®] formulation. All generics of OxyContin[®] must now possess abuse-deterrent properties to be granted FDA approval.

Interestingly, however, this does not apply to all cases of oft abused pain medicine. On May 10th, 2013, the FDA made a decision regarding the painkiller Opana[®] ER (oxymorphone). In response to a petition from Endo Pharmaceuticals Inc., the manufacturer of Opana® ER, the FDA decided to keep the original Opana[®] ER on the market for reasons of safety and effectiveness, and thus deemed generics that rely on the original formulation viable for approval upon submission of an abbreviated drug application. The FDA's decision was based on review of experimental data that makes this case unique from that of OxyContin[®]. The purportedly abusedeterrent Opana® ER is resistant to crushing, but not to cutting, grinding, or chewing. It can still be easily prepared for snorting using commonly available tools and methods. Contrary to Endo Pharmaceuticals' claim that the new Opana® ER tablets are resistant to "aqueous extraction," the FDA's evaluation concluded that these tablets can be readily prepared for injection. Furthermore, some studies suggest that the new Opana® ER has a higher percentage of abuse via injection than the original. Although

"Some studies suggest that the new Opana® ER has a higher percentage of abuse via injection than the original"

post-marketing surveillance is still inconclusive, these early findings are far from comforting.⁵

The FDA, in its public statement explaining its decision, announced that although the development of abuse-deterrent technologies to reduce opioid abuse is continuously encouraged, each new formulation that wants to make such a claim will be evaluated individually on its own merits.

NEWS



Page 4 VOLUME 2, ISSUE 9

SOURCES:

1) FDA approves abuse-deterrent labeling for reformulated Oxycontin. News and Events. U.S Food and Drug Administration Website. http://www.fda.gov/ NewsEvents/Newsroom/PressAnnouncements/ ucm348252.htm Updated April 16, 2013. Accessed May 29, 2013.

2) Oxycontin Prescribing Information. Purdue Pharma L.P. website. http://www.purduepharma.com/ wpcontent/uploads/ OxyContinPrescribingInformation_2013_04_16.pdf Updated April 4, 2013. Accessed May 29, 2013.

3) Cole EB, FDA bars generic version of OxyContin.

Pharmacy Times. Published online April 17, 2013. http://www.pharmacytimes.com/news/FDA-Bars-Generic-Version-of-Oxycontin Accessed May 29, 2013.

4) Weiss D, FDA refuses to remove generic Opana from market. *Pharmacy Times*. Published online May 21, 2013. http://www.pharmacytimes.com/news/ FDA-Refuses-to-Remove-Generic-Opana-From-Market Accessed May 29, 2013.

5)DA statement: original Opana ER relisting determination. News and Events. U.S Food and Drug Administration Website. http://www.fda.gov/Drugs/ DrugSafety/ucm351357.htm Updated May 10, 2013. Accessed May 29, 2013.

Helping Solve the Cruel Mystery [Continued]

By: Erica Dimitropoulos, Senior Staff Editor

Evident by its approval, belimumab has provided statistically significant relief to many lupus patients, particularly those with muscle pain and inflammation. While it is currently available as a monthly intravenous infusion, belimumab is undergoing Phase 3 Clinical Trials (BLISS-SC) to evaluate its efficacy and safety as a weekly subcutaneous injection, a dosage form that could change the lives of lupus patients.⁴ However, belimumab is not approved in patients with lupus nephritis or lupus vasculitis, has not been studied in combination with other biologic therapies, and has been shown to be less effective in African American patients who comprise the majority of the lupus population.⁵ These concerns are being addressed through several clinical trials aimed at treating the different subtypes of lupus.

On May 22, 2013 Mayor Michael Bloomberg and the New York City Council officially proclaimed May as Lupus Awareness Month.⁶ New York City was painted purple to spread awareness to "help solve the cruel mystery" of this unpredictable and misunderstood autoimmune disease.¹ Throughout the month, various informationals and promotions were held all around the city, hoping to catch the eyes of busy New Yorkers as they passed. For instance, Saks Fifth Avenue on 49th Street and 5th Avenue created a window display that urged people to "Put on Purple," otherwise known as POP, on Friday, May 17. Furthermore, on Saturday, May 18, the entire South Street Seaport was flooded with people who came out to support the Walk to End Lupus Now[™], despite the undesirable weather conditions.

Although much about Lupus has been discovered over the past few decades, a cure for this incomplete mystery is still being sought. Helping to spread awareness, even beyond the newly proclaimed month of May, can generate funds to promote research that may change the lives of millions worldwide. As Susan Golick, Founder and co-Vice President of the S.L.E Lupus Foundation, passionately pledged, "We will not stop until every person you might stop on the street can answer the question 'What is Lupus?"⁶

SOURCES:

1) Lupus is a Cruel Mystery. Lupus Foundation of America. Retrieved June 11, 2013, from http://www.cruelmystery.org/index.html.

2) Erica Jefferson. (March 9, 2011). News & Events. U.S Food and Drug Administration. Retrieved January 20, 2012, from http://www.fda.gov/newsevents/ newsroom/pressAnnouncements/ucm246489.htm.

3) La Cava, A. (October 4, 2010). Targeting B Cells with Biologics in SLE. *Expert Opinion on Biological Therapy*, 10(11), 1555-1561

4) Press Release. (December 15, 2011). GlaxoSmithKline and Human Genome Sciences initiate phase III trial of belimumab (Benlysta®) administered subcutaneously in subjects with systemic lupus erythematosus. *GlaxoSmithKline USA*. Retrieved January 20, 2013, from http://us.gsk.com/html/medianews/pressreleases/2011/2011-pressrelease-

5) JPMorgan Global Healthcare Conference 2012. (January 9, 2012). Human Genome Sciences Reports Progress with Commercialization of BEN-LYSTA® and Announces 2012 Goals at JPMorgan Healthcare Conference. *Business Wire*. Retrieved January 20, 2013, from http:// www.businesswire.com/news/ home/20120109006009/en/Human-Genome-Sciences-Reports-Progress-Commercialization-BENLYSTA®.

6) New York City Council Proclaims May Lupus Awareness Month. S.L.E Lupus Foundation. Retrieved May 22, 2013, from http://www.lupusny.org/news/ foundation-news/2013/05/22/new-york-citycouncil-proclaims-may-lupus-awareness-month TELL THE STORY. CHANGE LIVES. DOB CHANGE LIVES.

<u>Picture Source</u>: http://scope.connectwithmhs.org/wp-content/ uploads/2012/04/4378-POPBanner_300x350.jpg

impact on millions of people.

Read Something Interesting in the News? Want to share it with your Peers? Submit your articles to the Rho Chi Post! Send us an email: RhoChiPost@gmail.com

RHOKCH post VOLUME 2, ISSUE 9 Page 5



Coffeehouse Chats

By: Ada Seldin and Moisey Rafailov, PharmD Candidates Class of 2015

The "Coffeehouse Chats" is an annual Rho Chi Society Event that serves as a steppingstone to fostering professional relationships between students and faculty. The event provides a platform for students and professors to exchange experiences and ideas. This year, the event took place on April 23rd from 6-8:15 PM in the D'Angelo Center Coffeehouse. Approximately 50 students and 15 faculty members attended. The event commenced with dinner and provided guests an opportunity to meet. During this time, students and faculty enjoyed catered food over light conversation.

At 6:30 PM, attendees gathered around and Moisey Rafailov, president of the Rho Chi Society, introduced himself and the Executive Board. He thanked the audience for attending and started an icebreaker, during which each guest introduced him/ herself, year in the pharmacy program or faculty position, and something unique about him/herself. The icebreaker created a lighthearted and comfortable atmosphere, which was conducive to learning and networking.

The spotlight once again turned to Moisey, who began the discussion by asking the faculty, "How has pharmacy school changed since you were a student? What changes have you witnessed in the pharmacy profession?" In response, several faculty members spoke about changes in the curriculum that reflect the profession's shift towards patient-focused care and the expanding role of pharmacists. They also reminisced on carrying around large drug information textbooks because online resources, such as Lexi-Comp, were not yet available. In addition, some faculty shared that records were written by hand and stored using triplicates and carbon copies.

After this discussion, there was a short break for dessert, which included hot beverages, pastries, and fruits. Professors and students comfortably continued conversation. As dessert came to an end, guests returned to their seats and Moisey resumed the organized "chat." This discussion was primarily focused on current events. Moisey quoted an article from the Pharmacy Times, which stated: "A chorus is rising in the pharmacy community, calling for the profession to be accorded health care provider status. From a Doctor of Pharmacy candidate who has started an online petition calling on President Obama to join the cause to the CEO of one of the country's largest pharmacist associations who has identified it as a top priority, many feel that 2013 just might be the year when pharmacists win the right to be paid for the role they play in patient care."1

Pictures of Event on Page 8...

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!



Page 7 VOLUME 2, ISSUE 9

Then, Moisey questioned the audience. He asked, "This, of course, has to do with the role of a pharmacist as a non-physician provider. Do you agree that 2013 may be the year? What needs to be done in order for it to be so? And what is the importance of pharmacists receiving this status?" Dr. Arya took the floor, sharing her belief that this is not the year that pharmacists will achieve provider status, and that achieving this goal will require a big push from both pharmacists and students. Dr. Brocavich built upon her thoughts by mentioning that it is vital for students to keep abreast of pharmacyrelated news. Dr. Beizer added the importance of utilizing the many pharmacy organizations on campus to try to get involved on the national level.

Moisey then asked the audience, "As we know, all 50 states allow pharmacists to immunize. What do you think the importance of this is on the pharmacy profession?" Faculty members unanimously felt that the ability to immunize will help strengthen the pharmacist's image and further expand the role of a pharmacist in the community.

Another noteworthy topic of discussion was how pharmacists can deliver patient-centered services in the face of low reimbursement rates. Mr. Gary Corn and Dr. Aveena-Woods both emphasized that one major way to improve reimbursement rates is to counsel patients, explaining that the more we counsel, the greater the difference we will make in patient care. They stressed that the key is to transform the pharmacist's image and have patients associate pharmacists with counseling, rather than just dispensing duties. In other words, pharmacists need to create the demand for counseling in order to attain recognition for it. Further discussion stemmed from these ideas, such as the importance of students taking initiatives and never limiting oneself to the traditional roles of a pharmacist.

At the end of the night, Moisey concluded by urging students to apply what they had taken away from the discussion to their own practice. He reminded fellow students that faculty members can offer valuable insight and advice, and that it is in our power to make a difference in the pharmacy profession.

SOURCES:

1)Weiss D, The push for pharmacist provider status. *Pharmacy Times*. Published online January 8, 2013. http://www.pharmacytimes.com/news/The-Push-for-Provider-Status Accessed May 30, 2013.

Photographs published for this article are approved by and are the sole property of College of Pharmacy and Health Sciences, and the Rho Chi Post.

All Rights are reserved.

It is unlawful to use these images without expressed written consent.

You can obtain use agreements by contacting the photographer and our staff editors at RhoChiPost@Gmail.com

Share your Rotation Experiences!

Encounter any interesting drug information questions?

Write about them and send them to us at

rhochipost@gmail.com

EVENTS





Students and professors gathered together.



Students and professors interacting on a personal level.



Dr. Zito, acting dean, addressing the gathered crowd.



Professors converse about new pharmacy policies.



Students eagerly listening to their professors after hours.



Student pharmacist and professor discuss new policies.





Students and Professors conversing over dinner.



Dr Brocavich sharing his insights on Pharmacy.



Student Pharmacists gathered after the event.



Student Pharmacists celebrating the success of this years Coffeehouse Chats.

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

SUBMIT YOUR PHOTOGRAPHS

Send them to our editors at RhoChiPost@gmail.com

and we will feature your pictures in our next issue!



Noninvasive Cancer Screening—Will We Ever Get It Right?

By: Frances Sousonis, PharmD Candidate Class of 2017

Unfortunately, cancer is a disease about which many are able to share stories. All too often, beloved persons are diagnosed with cancer, or, more regrettably, loses their battle with the disease. Colon cancer is the third most common cancer in the United States and around 150,000 people each year are affected by it .1 Because early diagnosis makes an enormous difference in patient outcomes, many researchers work hard to find a detection tool that is more convenient, more accurate, and thus more appealing than the current procedures, such as colonoscopies. There are other on-going researches to find ways to handle different types of cancer. Cancer will continue to be treated with urgency, but new developments in the medical field may help strip the condition of its edge.

A new noninvasive test has been found to be effective in detecting cancer. While the test is originally designed for colon cancer, it may also be able to detect abnormal tissue growth associated with various other cancers.² This newly developed screening test called Cologuard seeks mutations in DNA through the patients' stool samples.² It may seem odd to the public to mail in these samples, but anything that could help discover cancer before it metastasizes is worth a shot. In essence, if proven to be superior, the stool sample testing will replace colonoscopy, which is the gold-standard for those at risk of colon cancer.

Currently, there are researches for methods other than Cologuard for cancer. These may involve diagnosis or treatment. For instance, Swedish scientists found that cardiac glycosides may play a role in killing cancer cells; however, the concentration of the drug in patient plasma would be at a rate that is unattainable.³ Other areas such as genetics, vitamin supplements, and immunotherapy are also being investigated.³ The cause for colon cancer is partly genetics, but certain vitamins and medications such as calcium, vitamin D, folic acid, and aspirin can help lower the likelihood of developing colon cancer.⁴ In immunotherapy, researchers are trying to develop vaccines that will either kill the cancer cells or prevent recurrence once the patient is in remission. The patient would have their own dendritic cells (cells of the immune system) altered *in vitro* and re-instilled to better fight off the cancer cells.⁴ Currently all of these options are only available in clinical trials, not in practice.

On the other hand, the newly studied noninvasive procedure, Cologuard, may be available to the public soon if further studies consistently support its benefits, but this seems unlikely. Questions are raised about whether the test is superior to the existing noninvasive procedures. Exact Sciences Corporation , the company that invented Cologuard, states that the test is about 92% accurate in detecting cancer.² The Cologuard test is no match for colonoscopy, because the latter can remove polyps—early indications of colon cancer—at the time of the procedure, thus possibly preventing cancer.²

In addition, Cologuard would most likely be marketed for several hundred dollars whereas the current noninvasive test that detects blood in stool samples—Fecal Immunochemical testing (FIT) — goes for about \$25.2 Dr. Deborah A. Fisher, who is unaffiliated with the testing of Cologuard, is a professor of medicine at Duke University, and is the consultant to Epigenomics—a company developing a test that could compete with Cologuard—says that Cologuard is no "holy grail."² Cologuard detects mutations in the DNA obtained from the stool sample, whereas other stool tests search for the presence of occult blood, or blood that cannot be seen with naked eyes, in the stool. Testing for blood in stool is much simpler and cheaper as opposed to testing the DNA obtained from stool, causing this drastic monetary difference.² The test uses the DNA sloughed off and disintegrated from intestine linings, which mostly consist of gut bacteria. Testing DNA this way is very challenging. Dr. David A. Ahlquist, a professor at the Mayo Clinic who helped develop the Cologuard test, says that "only 0.01 percent is the person's own DNA, and of that, only a tiny fraction would be from cancerous cells."2 In essence, the benefits of the new procedure don't seem to be adequate for Cologuard to be approved by the FDA.

Despite the doubts, the Exact Sciences Corpora-



Page 11 VOLUME 2, ISSUE 9

tion is persistent with its plan. The inventors say that because it requires less time to take a stool sample, more people would be willing to get screened. Actually proving the public's inclination would be difficult, putting the company's claims at a disadvantage. While the intent for Cologuard is admirable, more research is still needed.

The fight against cancer continues on. One can hope that with research, soon cancer will not be as devastating a disease as it is now.

SOURCES:

1) Cardiac drugs may fight colon cancer. US Pharmacist, A Jobson Publication Web site. http:// www.uspharmacist.com/content/s/111/c/18874/ Published January 20, 2010. Accessed May 3, 2013.

2) Pollack Andrew. Noninvasice cancer test is effective, study finds. New York Times Web site. http:// www.nytimes.com/2013/04/19/business/new-testdetects-most-colorectal-cancers-study-finds.html? ref=health&_r=0. Published April 18, 2013. Accessed May 3, 2013.

3) Felth J, Rickardson L, Rosen J, et al. Cytotoxic effects of cardiac glycosides in colon cancer cells, alone and in combinations with standard chemotherapeutic drugs. *Journal of Natural Products*. 2009;72 (11):1969-1974. http://pubs.acs.org/doi/ full/10.1021/np900210m. Accessed May 30, 2013.

4) What's new in colorectal cancer research and treatment? American Cancer Society Web site. http://www.cancer.org/cancer/ colonandrectumcancer/detailedguide/colorectalcancer-new-research. Updated January 17, 2013. Accessed May 30, 2013.

Get your writing published -Submit your articles to the Rho Chi Post!

Want to write, but need some ideas?

Visit our website:

http://rhochistj.org/RhoChiPost/Topics/

Register for an account to use this feature

For updates like our Facebook page: https://www.facebook.com/RhoChiPost



FDA Approves Dimethyl Fumarate for Treatment of Relapsing Forms of Multiple Sclerosis

By: Andy Zhang, PharmD Candidate Class of 2015

On March 28, 2013, the U.S. Food and Drug Administration announced the approval of TecfideraTM (dimethyl fumarate) for the treatment of relapsing forms of multiple sclerosis (MS) in adults.¹ TecfideraTM (dimethyl fumarate) will be the third oral drug used for the treatment of MS. The manufacturer Biogen Idec, a leader in multiple sclerosis drugs, has also produced other successful MS drugs in the past, such as Tysabri® (natalizumab) and Avonex® (Interferon β -1a).²

MS, the disease Tecfidera[™](dimethyl fumarate) treats, is a chronic inflammatory disease that targets the myelin in the central nervous system. Demyelination of axons can lead to irreversible damage, which inhibits proper conduction of nerve impulses in the central nervous system (CNS). This produces neurologic symptoms that vary from patient to patient in both severity and type.⁴ The exact pathogenesis of the disease is still unknown; however, there is convincing evidence that the disease is an autoimmune process in which the patient's own T-cells target the body's myelin and oligodendrocytes, the cells that produce myelin in the CNS.³ The disease occurs two to three times more often in women than in men, especially between the age of 20 and 50; however, it can affect both young children and older adults. About 85% of the patients are initially diagnosed with relapsing-remitting, and 50% of these patients progress into secondary-progressive MS within ten years of initial diagnosis.⁴ MS has debilitating effects on patients' quality of life.

Currently, there is no cure for MS. Treatments aim to break acute attacks and relapses, alleviate symptoms, and modify the course of the disease.³ Disease modifying agents can help reduce the disease activity and slow down the disease progression for patients with relapsing forms of MS. Examples of such agents include interferon-beta products such as glati-(Copaxone®), ramer acetate natalizumab (Tysabri®), fingolimod (Gilenya®), and mitoxantrone (Mitoantrone injection®).⁴ The standard intervention for acute exacerbations is short term intravenous injection of high-dose corticosteroids.³ Tecfidera[™] (dimethyl fumarate) is an immunomodulator that has been approved for the treatment of relapsing MS.

Two global, randomized, multi-center, doubleblind, placebo-controlled, dose comparison Phase III clinical trials (DEFINE and CONFIRM) were conducted to demonstrate the safety and efficacy of Tecfidera[™](dimethyl fumarate) in treating MS.⁵ The doses used in the trials were 240mg twice a day and 240mg three times a day. The primary end point of the DEFINE trial was the proportion of patients who relapsed within two years, and that of the CONFIRM trial was the annualized relapse rate over a period of two years.^{6,7} In the DEFINE trial, the percentage of patients who had at least one relapse of MS in two years was lower in both treatment groups compared to the placebo group (27% for twice daily, 26% for thrice daily, and 46% for placebo).6 Secondary endpoints also showed that patients in the both treatment groups took longer to relapse (87 and 91 weeks for twice daily and thrice daily, respectively, and 38 weeks for placebo group).⁶ Results from the CONFIRM trial showed that patients in both treatment groups had a lower frequency of relapse compared to the placebo (adjusted annualized relapse rate at two years of 0.22 and 0.22 for twice daily and thrice daily, respectively, and 0.4 for placebo).7

Tecfidera[™](dimethyl fumarate) has an overall favorable efficacy and safety profile compared to the other two oral agents fingolimod (Gilenya®) and teriflunomide (Aubagio®).⁸ While there are no direct comparisons done between the three oral agents, it seems that dimethyl fumarate (Tecfidera[™]) might be equally efficacious to fingolimod (Gilenya®) and be slightly better than teriflunomide (Aubagio®) for reducing relapses.⁸ Dimethyl fumarate has been used to treat psoriasis in Germany, and observational studies over the past 14 years has not shown serious or permanent adverse events, supporting a long history of safe use.⁹

Tecfidera[™](dimethyl fumarate) is available in120mg and 240mg capsules, and has a dosing regimen as follows: starting dose of 120mg twice a day orally for 7 days, followed by a maintenance dose of 240mg twice a day orally. The capsule

CLINICAL



Page 13 VOLUME 2, ISSUE 9

should be swallowed whole, and should not be crushed, chewed, or sprinkled on food. Most common adverse events are flushing and gastrointestinal events. Tecfidera[™](dimethyl fumarate) is Pregnancy Category C¹⁰ and may decrease lymphocyte count, so a recent complete blood count is recommended before initiation of therapy to identify patients with pre-existing low lymphocyte count.¹⁰ No serious infections were observed during the clinical trials even with the decreased lymphocyte count, and the incidence of infections were the same between patients treated with Tecfidera[™](dimethyl fumarate) and placebo.^{6,7,10}

With the introduction of Tecfidera[™] (dimethyl fumarate), there is now an alternative oral treatment which seems to have a safety profile comparable to the two other oral agents-fingolimod (Gilenya®) and teriflunomide (Aubagio®)—for MS. Some physicians and pharmacists might be enticed to try dimethyl fumarate over the injectible drugs as first line agent for treatment of MS, but further studies needs to be done to directly compare the different treatments before it can be proven to be a better first-line agent.

SOURCES:

1) Yao, Stephanie. FDA Approves New Multiple Sclerosis Treatment: Tecfidera. U.S. Food and Drug Administration. Updated March 28, 2013. Accessed May 24, 2013. http://www.fda.gov/NewsEvents/ Newsroom/PressAnnouncements/ucm345528.htm

2) Pollack, Andrew. 3rd Oral Drug to Treat MS Is Approved by the F.D.A. The New York Times. http://www.nytimes.com/2013/03/28/business/3rd-oral-drug-to-treat-ms-is-approved-by-the-fda.html?_r=0. Accessed May 24, 2013.

3) Talbert RL, DiPiro JT, Matzke GR, Posey LM, Wells BG, Yee GC. Chapter 64. Multiple Sclerosis. In: Talbert RL, DiPiro JT, Matzke GR, Posey LM, Wells BG, Yee GC, eds.Pharmacotherapy: A Pathophysiologic Approach. 8th ed. New York: McGraw-Hill; 2011. http://www.accesspharmacy.com/content.aspx? alD=7984977. Accessed May 24, 2013. 4) What Is Multiple Sclerosis? National Multiple Sclerosis Society Web Site. http:// www.nationalmssociety.org/about-multiple-sclerosis/ what-we-know-about-ms/what-is-ms/index.aspx. Accessed May 24, 2013.

5) Tecfidera (dimethyl fumarate) Clinical Development Background. Biogen Idec. http:// www.biogenidec.com/Files/Filer/USA/pdfs/Clinical-Trial-Fact-Sheet-FINAL.pdf. Accessed May 24, 2013.

6) Gold, R., Kappos, L., Arnold, D. L, et al;(2012). Placebo-Controlled Phase 3 Study of Oral BG-12 for Relapsing Multiple Sclerosis. New England Journal of Medicine 2012, 367(12), 1098–1107. DOI:10.1056/NEJMoa1114287. Epub 2012, Sept 20. http://www.nejm.org/doi/full/10.1056/ NEJMoa1114287#t=article. Accessed May 24, 2013.

7) Fox, R. J., Miller, D. H., Phillips, J. T, et al;(2012). Placebo-Controlled Phase 3 Study of Oral BG-12 or Glatiramer in Multiple Sclerosis. New England Journal of Medicine 2012, 367(12), 1087–1097. DOI:10.1056/NEJMoa1206328. Epub 2012, Sept 20. http://www.nejm.org/doi/full/10.1056/ NEJMoa1206328#t=article. Accessed May 24, 2013.

8) Hester, Stacy. New Drug: Tecfidera (Dimethyl Fumarate). Pharmacist's Letter [Internet]. [cited May 24, 2013]; 29/-(5):290512. Available from: http:// pharmacistsletter.therapeuticresearch.com/pl/ ArticleDD.aspx? nidchk=1&cs=STUDENT&s=PL&pt=6&fpt=56&dd= 290512&pb=PL

9) Killestein J, Rudick RA, Polman CH. Oral treatment for multiple sclerosis. *The Lancet Neurology*. 2011;10 (11):1026-34. http://search.proquest.com/ docview/900472684?accountid=14068

10) Tecfidera [Package Insert]. Available at http:// www.tecfidera.com/pdfs/full-prescribinginformation.pdf. Accessed May 24, 2013.

VOLUME 2, ISSUE 9 Page 14

Pay to Delay: The Honest Truth

By: David Ong, PharmD Candidate Class of 2014

Our current healthcare system receives much criticism from the press as well as the public. Big pharmaceutical companies ("Big Pharma") have consistently been characterized as part of the problem. Most of the blame for high drug costs is levied on Big Pharma. One of the criticisms is that the profits made by large pharmaceutical companies outweigh the benefits provided by the drugs they manufacture. Such allegations need to be viewed in the light of the fact that it is these profits that drive new drug discovery and help the pharmaceutical companies stay competitive in the market.

Patenting drugs for a significant period of time is one way the government compensates Big Pharma for their expenditure on research and development. During the patent life of a drug, only the innovator can legally sell the drug in question. This patent life can be extended if the innovator proposes a new indication for the same drug. The FDA then approves the new indication and patent. A generic manufacturer can file a suit alleging that the new drug indication proposed by the innovator is 'weak.' To mitigate legal expenses, brand-name drug manufacturers can offer financial compensation, or settlements, to generic manufacturers to drop the case. Now, however, there is a legal uproar where consumer advocates, healthcare organizations, the Federal Trade Commission, and retail outlets are challenging the out-ofcourt settlements between brand-name drug manufacturers and generic drug manufacturers.^{1,2,3}

According to the Federal Trade Commission, generic companies win about 73 percent of such patent challenges. However, settlements financially benefit certain generic companies more than being given a piece of the market after winning a trial.¹ For example, when Solvay, the brand-name manufacturer now a part of AbbVie Inc.—who holds the patent for Androgel® (testosterone gel for topical use), settled with Watson Pharmaceuticals, who had won FDA approval for their generic version. Watson Pharmaceuticals agreed to delay marketing their generic counterpart for another nine years in exchange for \$42 million per year.^{1,2}

A generic drug is sold for as much as 85% less cost than the brand, according to Solicitor General Donald Verrilli, causing enormous financial damage to the brand-name companies.^{1,2} Since both generic drug manufacturers and brand-name drug manufacturers benefit from settling, settlements seem to be a legitimate and expedient way to resolve expensive patent litigations in a timely fashion.³

Protestors have coined the term "pay to delay" to describe these settlements, whereas advocates prefer the term "reverse settlements."¹ Advocates include both the generic and brand name drug manufacturers. While these two parties are usually on the opposite sides of the suits in question, they are both pro-settlement because it is mutually beneficial. 1,2

One must first understand that these settlements are for cases involving patent extensions. Protestors claim that these settlements increase the financial burden on patients and the healthcare system. However, settlements proposed by the brand-name drug manufacturer usually include a shortened patent extension and a financial incentive. Thus, these settlements actually help consumers rather than hurt them.²

The patents that are usually targeted by generic companies are those for popularly prescribed medications.² If settlements are banned, brand-name drug makers will bear tremendous legal costs. If patent extension cases favor the generic company in court, the brand-name company will lose its patent extension. The brand-name company will be stripped of years of potential financial earnings. This will limit their ability to research new drugs.



Page 15 VOLUME 2, ISSUE 9

Furthermore, if patents are discontinued, shortened, or otherwise modified, the incentive to innovate will diminish because of the inadequate reimbursement for the resources spent in research and development. Those who call such settlements unlawful and anticompetitive are at a risk of being myopic, and they are actually opposing innovation and advancement in the pharmaceutical and medical industries.

SOURCES:

1) Totenberg N. Supreme Court Hears 'Pay to Delay' Pharmaceutical Case. National Public Radio Web Site. http:// www.npr.org/2013/03/25/175043758/supremecourt-hears-pay-to-delay-pharmaceuticalcase#mainContent. 25 March 2013. Accessed April 3,2013.

2) Holland JJ. Court: Can Drug Companies Pay to Delay Generics?. Yahoo News Web Site. http:// news.yahoo.com/court-drug-companies-pay-delaygenerics-140009962--finance.html. 24 March 2013. Accessed April 3, 2013.

3) Singer N. Deals to Restrain Generic Drugs Face a Ban. New York Times. 12 January 2010: B1.http:// www.nytimes.com/2010/01/13/ business/13generic.html?

ref=genericdrugspharmaceuticals

Interview with Dr. Omudhome Ogbru, Founder of RxEconsult LLC

By: Steve Soman, PharmD



I see that you got your PharmD at the University of the Pacific. Looking back, what made you choose pharmacy and how has this changed over the years of your practice (if it has)?

I became a pharmacist because I like to care for others and I also saw the unique role and value of pharmacists in healthcare.

Even before acceptance to pharmacy school, I knew I would be a clinical pharmacist. The diverse roles and career opportunities that a PharmD provides was also very attractive. Since you are a Rho Chi member from 1993, what do you think of Rho Chi Post and our mission? Do you believe Rho Chi Post is a viable student publishing platform?

Rho Chi Post is an innovative idea and a great platform for students to learn and share knowledge. Fostering communication, learning, and promoting the pharmacy profession is the responsibility of every pharmacist. I commend your school for instilling these values in their students and the Rho Chi Post editors for their effort.

You have spent a few years in the pharmaceutical industry. How did you transition over to the industry? What was the driving factor in pursing that practice after receiving your PharmD?

My first opportunity after completing a residency was in academia and clinical practice. After a few years, I decided to explore other career opportunities and the pharmaceutical industry seemed interesting and full of promise. I was curious about how drugs are discovered, produced, and made available to patients.

You have held various administrative roles in Bristol-Myers Squibb (BMS), Baxter BioScience, and The Medicines Company. Can you describe your experiences throughout your



years in these companies and any advice you would offer new students that would be looking to join the industry?

There are many opportunities for pharmacists beyond retail or hospital practice. Students should be curious, ask questions, read and learn about all the possible career opportunities, and connect with people who can provide insight. There are many different types of jobs for pharmacists in the pharmaceutical industry.

Students who are interested should spend an elective rotation at a pharmaceutical company and should strongly consider completing a fellowship or residency program. Read <u>Pharmaceutical Industry Jobs</u> <u>for Pharmacists</u> and similar articles published on RxEconsult for more information.

What made you leave the pharmaceutical industry? What was the driving factor in the creation of <u>RxEconsult</u>?

I took a break from the pharmaceutical industry to pursue an idea, which became RxEconsult. I believe that healthcare businesses and professionals need their own network to help increase their visibility, for collaboration, learning, and to find opportunities.

The RxEconsult premise is simple—share what you know and people will find you, learn about you, and follow you. RxEconsult helps members establish their professional and business identity and greatly expand their network, leading to opportunities. Simply stated, share knowledge and be discovered.

The focus of the RxEconsult community is the exchange of healthcare knowledge through publication of articles and other content. It is a diverse community open to all healthcare professionals or students and it is free.

How can RxEconsult serve as a conduit for professional growth and development for pharmacists, and more specifically, the pharmacy students?

RxEconsult provides an opportunity to network with pharmacists from all areas of pharmacy practice and other healthcare professionals.

RxEconsult provides an opportunity to educate other healthcare professionals about the pharmacy profession because it is a community of all healthcare people. By publishing articles, students and professionals can showcase their knowledge, educate others, and greatly increase their visibility. Students and professionals who have published articles on RxEconsult are reaping the rewards of increased visibility and building their resumes. Students can use the RxEconsult <u>healthcare job board</u> to find pharmacy jobs posted across the internet.

What makes RxEconsult different or unique from other medical information websites such as WebMD?

RxEconsult is a fully developed professional healthcare social network. Content on RxEconsult is member generated and as the website grows the collective depth and breath of knowledge in the community should surpass healthcare information websites.

RxEconsult is a platform where all healthcare people can share their knowledge, be experts, increase their visibility, network, and find opportunities. Our focus is professional and business development.

What do you think is the role of social media in pharmacy or in healthcare in general as the world becomes more dependent (and interconnected) via the internet?

Social media is a platform for pharmacists to share, learn, network and collaborate. It enables information to be easily distributed and digested by many.

We can leverage social media to change the perception of the pharmacy profession and increase our visibility. There is a gap in quality healthcare information on the web. Pharmacists can help bridge these gaps by publishing on websites like RxEconsult.

We are conducting a pharmacy faculty/student survey about use of social media.

Please complete the <u>survey</u>.

Thank you for the opportunity to share RxEconsult with students and faculty of St. John's University College of Pharmacy and Health Sciences. Rho Chi Post editors and contributors exemplify the entrepreneurial spirit that will advance the pharmacy profession. I look forward to following your careers.

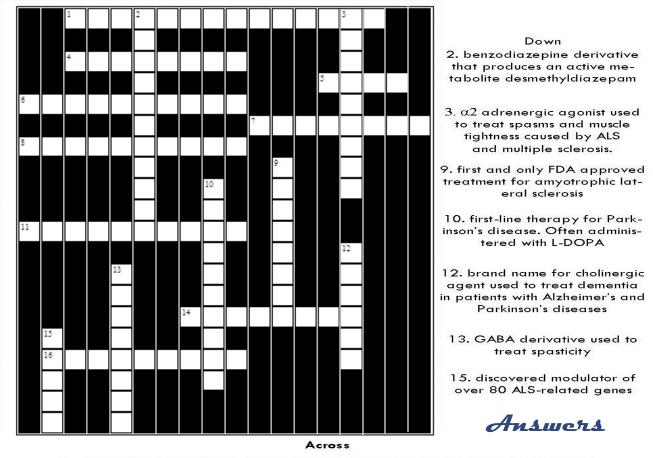




Crossword Puzzle: Drug Therapy for Motor Neuron Disease

By: Tamara Yunusova, Senior Staff editor

June is Motor Neuron Disease (MND) awareness month. MND is a group of progressive neurological disorders which are characterized by degeneration of motor neurons, cells that control voluntary muscle activity such as speaking, walking, breathing, and swallowing. The 5 most common diseases that fall into this category include: Amyotrophic Lateral Sclerosis (ALS), Primary Lateral Sclerosis (PLS), Progressive Muscular Atrophy (PMA), Progressive Bulbar Palsy (PBP), and Pseudobulbar Palsy. Unfortunately, no cure or standard treatment yet exists for MND. Current drug therapy includes cocktails of muscle relaxants, antisialogogues, anticonvulsants, antidepressants, NSAIDS, and in certain instances, opiates.



muscarinic acetylcholine antagonist that does not cross the blood-brain barrier
4. muscarinic acetylcholine antagonist which reduces salivation

5. abbreviation for a novel class of androgen receptor ligands. Potential therapy for muscular atrophy.

6. muscle relaxant which exhibits increased bioavailability when taken with food

7. administered in combination with DOPA decarboxylase inhibitor in order to prevent peripheral side effects

8. GABA analogue used to treat epilepsy and neuropathic pain

 dopamine agonist; one of the three FDA approved medications to treat Restless Leg Syndrome.

14. brand name for muscle relaxant which is used off-label for treating fibromyalgia

16. forms desglymidodrine metabolite which activates α -adrenergic receptors to elevate blood pressure

Page 18 VOLUME 2, ISSUE 9

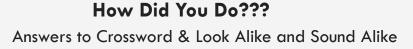
post

RHO^RCHI

	LOOK-ALIKE	1) Competitively inhibits postsynaptic alpha 1-adrenergic receptors		
(2) A calcium channel blocker used to treat hypertension	A)	Catapres
	SOUND-ALIKE	3) A high-alert medication – The Institute for Safe Medication Practices (ISMP) includes this medication (I.V. formulation) among its	B)	Carisoproc
		list of drug classes which have a heightened risk of causing significant patient harm when used in error	C)	Carvedilol
	By: Frances Trosa,	4) Indicated for short term use (2 – 3 weeks) treatment of acute musculoskeletal pain	D)	Cardura
Pł	harmD Candidate 2015	5) Has nonselective beta-adrenoceptor and alpha-adrenergic blocking activity	E)	Cimetidine
	Many drugs LOOK – ALIKE	6) Carries a U.S. boxed warning stating that its use is contraindicated for treatment of perioperative pain in the setting of coronary artery bypass graft surgery	F)	Cardene
	OR	, , , , , , , , , , , , , , , , , , , ,		
	SOUND- ALIKE	7) Stimulates alpha2-adrenergic receptors and is used for the treatment of hypertension	G)	Cataflam
	Causing them to be easily mixed up in practice. Can YOU match these	8) Carries a U.S. boxed warning stating that this drug is only indicated for patients with life – threatening arrhythmias due to the high risk of toxicity	H)	Cardizem
	facts with the correct medication?	9) Available with a prescription or OTC. OTC preparations are indicated for the prevention or relief of heartburn, acid indigestion or sour stomach	I)	Cordarone
	Answers	10) Indicated for the treatment of symptoms of dry mouth in patients with) (L	Cevimeline

PUZZLES





		1 G	L	Y	2 C	0	Р	Y	R	R	0	L	A	3 T	E		
					L									Ι			
		4 A	Т	R	0	Р	Ι	Ν	E					Z			
					R								5 S	A	R	Μ	
6 M	E	Т	A	Х	A	L	0	Ν	E					Ν			
					Z					7 L	E	V	A	D	0	Р	Α
s G	A	В	A	Р	E	Ν	Т	Ι	Ν					Ι			
					Р						۶R			Ν			
					A			10 S			Ι			E			
					Т			E			L						
11 R	0	P	Ι	Ν	E	R	0	L	E		U						
								E			Z			12 E			
				13 B				G			0			Х			
				A				Ι			L			E			
				С			14 F	L	E	Х	E	R	Ι	L			
	15 G			L				Ι						0			
	16 M	Ι	D	0	D	R	Ι	Ν	E					Ν			
	6			F				E									
	0			E													
	4			Ν													
1. D 2. F 3. H 4. B 5. C 6. G 7. A 8. I 9. E 10. J											J						

Do you enjoy our puzzles?

Send us a suggestion for a brainteaser at

rhochipost@gmail.com

We will feature your work in our next issue!



RHO CHI POST: EDITORIAL TEAM



@ Katharine Cimmino (5th 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 (5th Year, STJ; Co-Copy Editor [Content-Focused])

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



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

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



EDITORS

@ Aleena Cherian (6th 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!



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

We as future healthcare professionals owe it to our patients and ourselves to become aware and current on the events affecting our profession. The Rho Chi Post is our way to learn new things and stay in touch with the pharmacy world, on- and off-campus. I have gained so much from reading previous publications and feel privileged to have the opportunity be a part of the team. Feel free to reach out to me with suggestions and comments.

@ Erica Dimitropoulos (5th 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!



Page 21 VOLUME 2, ISSUE 9

RHO CHI POST: EDITORIAL TEAM



@ Tamara Yunusova (3rd Year, STJ; Senior Staff Editor)

My name is Tamara Yunusova, and I am a 3^{rd} 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 (5th 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



@ Diana Gritsenko (5th 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 (5th Year, STJ; Staff Editor)

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



@ Sang Hyo Kim (2nd Year, STJ; Staff Editor)

Advancements of technology and developments of new medicines, prolonging the lifespan and improving the quality of life, have increased the geriatric population. In years to come, pharmaceutical industries and healthcare systems will persistently work to find solutions to changing demands and new problems of the society. Through the Rho Chi Post, I wish to learn, educate, and prepare myself and others for the future.



@ You!

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

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

RHO^RCHI post

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.

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

THE RHO CHI POST

MISSION

The Rho Chi Post is a monthly, electronic, studentoperated, 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
- 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

St. John's University COLLEGE OF PHARMACY AND HEALTH SCIENCES

UPCOMING EVENTS

Jun 17-21: Principles & Practice of PainMeds Cambridge, Massachusetts

Jun 19: Seventh Annual Charles I. Jarowski Industrial Pharmacy Symposium 8:00AM St. John's, Queens NY

Jun 19-21: Structure Based Drug Design Revere Hotel, Boston, Massachusetts

Jun 23-27: 49th Annual DIA Meeting Convention Center, Boston, Massachusetts

Jun 27: International Workshop on Clinical Pharmacology of Hepatitis Therapy Cambridge, Massachusetts