

RHO Rx CHI post

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- 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

Migraine Relief	1
Pharmacists in the ER	3
Tailored Tablets	4
DIA Annual Meeting	6
Pediatric Hypertension	7
Clinical Corner	9
Drug Shortages	15
Herbals & Supplements	18
Look Alike Sound Alike	19
Puzzle Answers	20
Quote of the Month	20
Editorial Team	21
Upcoming Events	23
About Us	23

Migraine Relief at the Push of a Button

By: Davidta Brown, Senior Staff Editor

A new therapeutic device has seemingly leapt from the pages of a science fiction novel and into the hands of migraine sufferers around the world. Worn over the forehead and sending electromagnetic stimulation directly into the supraorbital trigeminal nerves, the cranial nerve stimulator offered by Belgian biotechnology company Cefaly Technology is, clearly, turning heads.¹ The nerve stimulator, referred to as Cefaly®, attaches to an adhesive electrode placed on the forehead of the headache sufferer.² Through the electrode, the device generates micro-impulses that target the superior nerve endings of the trigeminal nerve.^{2,3} Cefaly® is a battery-operated device which, with the recommended 20 minutes of daily use, purports to reduce the frequency and intensity of migraine attacks at the minor expense of a mild tingling sensation.^{2,4}

For Cefaly Technology, this particular cranial nerve stimulator is one of several devices under development. The company launched its Cefaly® project in 2005, with the first device of its kind presented in Bologna, Italy in 2006.⁵ The Cefaly® device was introduced to the French market in 2012, and received approval from the United States FDA in 2014.⁵ The model of the device approved in the US is somewhat less complex than the European model – the US model has one “standard program” of electromagnetic impulses, while the European model has three, is programmable, and has fully adjustable session duration and intensity.¹ The European model of Cefaly® allows patients to increase the intensity of the impulses over time, which, in theory, should provide increasingly more effective and lasting relief from symptoms.²

There have been a few clinical studies evaluating the safety, efficacy, and adverse effects of Cefaly®, and, in general, all of the results have been similar. One trial tested the safety and efficacy of trigeminal neurostimulation with the

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transcutaneous stimulator in a double-blind, sham-controlled study.⁶ Sixty-seven patients, each of whom experienced at least two migraine attacks per month, were randomly assigned either a functional device or a “sham”, placebo device.⁶ Patients used Cefaly® as directed in at least one 20 minute session a day for three months, and the effects were evaluated as a reduction in the number of migraine days per month.⁶ The mean number of migraine days decreased significantly among individuals who received treatment, from 6.94 to 4.88 ($p=0.023$), but not among patients who had the placebo device; those patients experienced a reduction from 6.54 to 6.22 monthly migraine days ($p=0.608$).⁶ No adverse events were reported in either group during the course of this study, and the monthly intake of anti-migraine drugs also decreased significantly among the patients in the experimental group.⁶

Another larger safety study was conducted with 2,313 participants, in the hopes of screening for adverse effects in a larger population.⁷ In this study, participant selection was limited to individuals who were taking triptan drugs for migraine relief and who rented the Cefaly® device for a 40 day trial.⁷ After a testing period that lasted an average of 58.2 days, participants were assessed via phone interview to determine their satisfaction or lack of satisfaction with the device, as well as the presence of any side effects or technical difficulties.⁷ “Satisfied” study participants were those who wished to continue treatment with Cefaly® and were willing to purchase the device.⁷ Data collected at the end of the study showed that 54.4% of participants were satisfied with the results of the treatment. 4.3% of the individuals under study experienced one or more adverse events, but all of these were minor and fully reversible, such as local pain or irritation, sleepiness during treatment, or headache after using the device.⁷

The devices that were rented out to study participants each included software that monitored usage, and this data was collected and analyzed by researchers after the observation period.⁷ The data

showed that of the 46.6% who were not satisfied with the effects of Cefaly®, 48.6% had not used the device for the recommended period of time, and 4.46% had never even turned it on.⁷ Taken together, all of these results led researchers to pronounce the transcutaneous neurostimulation provided by Cefaly® a “safe and well-tolerated treatment for migraine headaches”.⁷ Furthermore, the results of these safety studies have piqued curiosity about the device’s possible use as a treatment for other disorders, including insomnia.⁴ In the end, time in the hands of the public will be the most important test of the device’s value, and will answer the question of whether Cefaly® is the solution that millions of migraine sufferers have been hoping for.

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The Role of Pharmacists Expanding into the Emergency Room

By: Sherin Pathickal, PharmD Candidate c/o 2016

In 2006, the Institute of Medicine reported that over 1.5 million people in the US suffered from a medication error, errors that not only cost the economy billions of dollars, but endangered countless lives.¹ Each year, approximately 7,000 deaths occur due to preventable medication related errors.² These errors include, but are not limited to, the wrong dose, the wrong formulation, and the wrong medication being administered.¹ The reasons for medication errors are numerous: medical professionals being overworked and rushed, misreading prescriptions, or administering incorrect sound-alike/look-alike drugs. With the number of medication related errors remaining at a dangerous high, it is clear that additional safeguards need to be set in place to protect the patients' lives.

Fortunately, the Children's Medical Center of Dallas appears to be developing a plan to do just that. It recently employed ten around-the-clock pharmacists who continually review orders placed by physicians and recommend changes, keeping the patient's wellbeing a top priority.² Such vigilance is especially important at medical centers such as this one, as it caters to children and adolescents primarily. The pediatric population was once treated as "little adults," but it has become clear that their metabolism of certain drugs is drastically different from that of adults. Drug treatment that ignores this fact may result in under-dosing, overdosing, and toxic serum concentrations.² Studies have indicated that children are up to three times as likely to suffer from a medication error as adults.² With physicians and pharmacists working together, a pediatric patient's health information such as the weight, allergies, and medication history should all be thoroughly reviewed prior to prescribing and administering a drug.²

Prior to the addition of clinical pharmacists in select hospitals across the country, prescribers depended heavily on the electronic medical record sys-

tems to find potential errors. However, these systems were unable to catch all of the potential errors in the emergency room. Dr. James Svenson, a professor at the University of Wisconsin, recently performed a study that looked at the potential risks associated with utilizing the electronic medical record system alone and found that nearly a quarter of a all prescriptions written for children had errors that were not discovered by the system.² Of the prescriptions written for adults, nearly 10% were found to still contain errors.² It is clear that even with electronic systems in place, additional help and surveillance provided by pharmacists is needed.

The study performed at the Children's Medical Center is just one of many studies that exemplify the important role of pharmacists in the emergency department. In 2011, a similar study was performed in Albuquerque at the University of New Mexico.³ The University boasts a well known level 1 trauma center, and the data compiled there compared the frequency of medication related errors with and without the input of pharmacists. The results clearly demonstrated the additional security provided by having qualified pharmacists present, as errors were found to be 13 times more frequent without a pharmacist.³ The data compiled looked at a period of 3 months in 2009.³ The site only has pharmacists on duty for ten hours, so the same three months were compared. Over the three months, 2.5% of the patients monitored suffered from an adverse medication error while a pharmacist was present as opposed to 30.3% without a pharmacist.³ Of note, results indicated that the medications with the most errors were found to be antibiotics, then pain medications, followed by cardiac and GI medications.³

With the number of medication related errors on the rise, it is clear that the pharmacists needs to expand into the emergency room as well as other critical care units. Prescribing errors such as incorrect

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medication, dosage, or drug form, result in adverse events. If proper care is not taken to review the patients' profile, many lives could be in danger. Although this is a concern at any department in a hospital, it is highly problematic in the emergency room, where quick thinking is needed at all times. Pharmacists, as drug experts, should take on a more hands-on role to ensure the safety of patients and other health care professionals.

Tailored Tablets

By Azia Tariq, Staff Editor

Truly personalized medication is the goal of researchers in the pharmaceutical and biotechnological industries. For example, when a patient requires a precise dose that is not manufactured as a tablet, the tablet will be broken up in order to deliver the dose as close as possible. Not only is the process inaccurate, some tablets cannot be tampered with, due to the stability and efficacy of the active ingredient, and also due to possible harm it may cause the patient.¹ Tablets that are scored may be safe, but time-release formulations and some coated pills may prove difficult or harmful. How can these types of formulations be accurately delivered to a patient?

The answer to this common medical obstacle is a prototype system that uses a mathematical formula and inkjet technology to draft precise medication dosages for specific patients. These tailored dosages are created as either tablets or melted formulations via the prototype machine, which is approximately the size of a large laser printer, and provides a methodical option for reducing the need of splitting medication manually for ideal doses.²

Commercializing the prototype could revolutionize the way we administer medicine. Pharmaceutical companies and manufacturers make a few dose levels based on clinical studies that examine the average recommended dose. "Many drugs have a minimum effective level, so you need to meet that, and many of them have a toxic level. The closer you get to it, the more side effects there are." explain both Gintaras Reklaitis of Purdue University and Kathryn Gedge, a professor of chemical engineering.³ Incorporating the device in the process of creating medication enables medical personnel to address this and minimize potential side effects from a mistaken higher dose.

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porating the device in the process of creating medication enables medical personnel to address this and minimize potential side effects from a mistaken higher dose.

The procedure for using the prototype machine has been established. First, blood samples are drawn from the patient after a small quantity of the drug has been administered. Data from those samples are then combined with information from clinical studies of a larger number of patients which would then be utilized in mathematical models to determine the proper dose for a particular patient.⁴ A portable technology then dissolves or melts the drugs with polymers and uses drop-on-demand inkjet printing technology to deposit exact quantities of the active pharmaceutical ingredients (APIs) directly onto edible substrates, also known as tablet molds and films. The use of this technology allows for control over the material properties, drop size, drop dynamics, and drug solid state form.²

Reklaitis, who is working with a team of researchers from Purdue, says "We envision that in its final form the printing will be done in an automated fashion. The pharmacist could key in the dose, the machine prints 20 tablets, and off you go."³

The team of researchers has built a prototype and is now working towards the commercialization of the device with funding by the National Science Foundation. Though the technology has only recently been implemented and is only in its infant stage, it could drastically alter how medicine is proffered.

BACK TO COVER

Such a technological advance can be a solution to the critical issue of splitting difficult formulations and can be beneficial in the creation of high-potency drug forms, combination drugs with multiple APIs, or individualized medicinal products tailored to a specific patient.² With the introduction of new technology, however, there is the possibility of backlash and a refusal to adapt to newer methods over tried and tested ones. Pharmacists and healthcare providers would need to be convinced that there is a legitimate demand for the device. Cost could be an additional factor that could hinder the device's commercialization and widespread use in pharmacies in the near future.

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DIA: 50th Annual Meeting 2014

By: Melissa Roy, Co-Copy Editor [Graphics Focused]

DIA stands for Drug Information Association. It is an organization that strives to provide both educational and professional development opportunities for individuals working in pharmaceutical and medical product development-related fields, as well as a global, unbiased forum for the exchange of information across multiple disciplines of programming and publications.¹ DIA was founded in 1964, and the 50th annual meeting was hosted this past June in San Diego, CA. The conference was held from June 15th to 19th and members gathered from all over the globe to contribute to the world of medicine.

As a student, I had the unique opportunity to attend this conference with access to all sessions at a fraction of the cost. We were given some guidance on sessions that might be of interest, but were told from the very beginning to take some chances and branch out. I took that advice to heart and tried a sprinkling of several tracks that were offered. There were over 21 tracks, from public policy to professional development and orphan diseases. Within the tracks there were over 260 sessions that you could attend over the course of four days. I felt that there were moments where the information provided were beyond my understanding; however, the way people were soaking up the information showcased how valuable the sessions were to the pharmaceutical world. For example, I attended an FDA session on new social media guidelines and wondered how the information could be important, but as they opened the session for Q&A I was amazed that there were a slew of questions to be answered.

These events are a great opportunity for students is to branch out and meet new people. The connections that you make today may become the link to an internship, or even a job, tomorrow. Profes-

sionals that attend these conferences are practically inaccessible otherwise, and the meeting provides students an opportunity to find mentors. Each connection, if utilized correctly, can become a stepping-stone.

While this conference was a wholesome educational experience, another major aspect of these conferences is the ability to visit a new city each time. This was my first trip to the West Coast. San Diego is a very welcoming city; we were greeted with signs that read, "San Diego welcomes attendees of the DIA Annual Meeting". The city is reputed for perfect weather at all times and a gorgeous harbor, and is also known as "America's Finest City". San Diego's nickname is aptly earned and I can't wait for the next opportunity to return.

Many people asked me what I learned from attending this annual meeting. I gave everyone the same response- it wasn't so much what I learned but what I experienced that was invaluable. This conference was great because of the total experience. It helped me build more confidence; both through the ability to travel to a new city and by allowing me to interact with people and form new relationships. I expanded my knowledge through the vast variety of information that was made available to me; which I have found useful in my work place and on rotations. Most importantly I simply grew, as a student, a future pharmacist, and a person through all of my experiences at this conference.

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Pediatric Hypertension

By: Anthony Botte and Tyler Valente, PharmD Candidates c/o 2016

Diseases which are prevalent within the pediatric population require distinct protocols for treatment accompanied by the utmost care and precision. Pediatric hypertension (HTN) is one disease state in particular that has come to the forefront of medical practice in the United States over the past decade. Reasons for this include an increase in the prevalence of cardiac abnormalities, improvements in diagnosing, and a rise in childhood obesity. It is estimated that 3% to 5% of the pediatric population is currently affected by this condition.¹

Children three years and older should have their blood pressures checked via auscultation at each visit to their healthcare provider and measured via sphygmomanometer if the readings appear elevated. Childhood HTN is diagnosed based on average systolic blood pressure and/or diastolic blood pressure readings that are greater than or equal to the 95th percentile on three or more consecutive office visits. An individual's blood pressure percentile is calculated based on his/her sex, age, and height.²

Pediatric HTN causes immediate harm to a child, but also has implications on his/her health in the future. Critical concerns for treating pediatric HTN include avoidance of some non-specific symptoms such as headache, vertigo, nasal bleeding, nausea, and vomiting triggered by hypertensive urgency, and preventing target organ insufficiency. Among the long-term consequences of not treating pediatric hypertension are adult HTN, cardiovascular disease, and insulin resistance.^{2, 3}

Non-pharmacologic treatments such as lifestyle modifications can be effective at lowering blood pressure and decreasing risks of cardiovascular disease. The Dietary Approach to Stop Hypertension (DASH) diet is commonly considered for pediatric patients (12 months of age and older) with HTN. DASH encourages a diet regimen that consists of fruits, vegetables, non-fat dairy products, fiber, and low amounts of daily sodium consumption. Besides dietary modifications, weight loss for overweight patients, as well as physical exercise for all patients, is recommended. A pediatric patient can stay active by walking, biking, playing sports, and completing

household chores.^{4, 5}

Pharmacologic interventions appear to be the most effective forms of treating pediatric HTN. Since there is limited data regarding the long-term effects of antihypertensive drugs on children's growth and development, clear-cut indications should be established before initiating therapy. These indications include symptomatic HTN, secondary HTN, established hypertensive target-organ damage, and failure of nonpharmacologic measures.² Since all classes of antihypertensive drugs have been shown to lower blood pressure in children, the physician's judgment dictates which medication should be used to initiate therapy. No matter which class of medication is selected, treatment is initiated at the lowest recommended dose and titrated upward until optimal blood pressure is achieved. After the highest possible dose has been reached, or if the patient experiences adverse effects from the medication, a drug from another class is added onto the regimen. The most commonly prescribed anti-hypertensive drugs for pediatric patients fall into four main classes: Angiotensin-Converting Enzyme Inhibitors, Angiotensin Receptor Blockers, Calcium Channel Blockers, and Beta-Blockers. Among the four classes, Angiotensin-Converting Enzyme Inhibitors have the most evidence supporting their use in the pediatric population when treating HTN.⁶ Although diuretics are commonly used to treat pediatric HTN, no large studies have been performed to date.

Pharmacists can play a large role in the detection and treatment of pediatric HTN. They can record blood pressure, promote healthy lifestyles, collaborate with the physician to select the best course of treatment, and verify pediatric doses.⁵

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2. Staff Designer
 - Web based: Commitment per issue: Redesign and upkeep of the website
 - Graphic based: Commitment per issue: Any graphic designing that goes into creating the issue.
3. Staff Editor: Commitment per issue: 1 contribution, 2 articles edited
 - Note: for this position you need to show past editing experience.

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RHO CHI POST
CLINICAL CORNER

Antidepressants- Selective Serotonin Reuptake Inhibitors & Serotonin- Norepinephrine Reuptake Inhibitors

By: Melissa Roy, Co-Copy Editor [Graphics Focused] Luxi Wang, PharmD candidate 2015, Eleni Catsimalis PharmD, Roman Fazylov PharmD & Beatrisa Popovitz, Senior Staff Editor

Antidepressants- Selective Serotonin Reuptake Inhibitors

Name	Dosing	ADRS	Counseling/ Considerations	Availability
Celexa (citalopram)	<p>Adults: Depression: Pts. <60y/o: 20mg PO once a day. MAX: 40mg</p> <p>Pts. ≥60 y/o- MAX: 20mg PO daily (increase risk of QTc prolongation)</p>	<p>Nausea Xerostomia Diaphoresis QTc prolongation (>40mg) Somnolence Insomnia</p> <p>BBW: increase risk of suicidal thinking and behavior ≤24y/o pts. w/ Major Depressive Disorder (MDD) and other psychiatric disorders</p>	<p>Stop SSRI 14 days prior to starting and MAOI (vice versa)</p> <p>Max: 20mg in pts. using CYP2C19 inhibitors (cimetidine, omeprazole)</p> <p>Allow 6-12 weeks after initiation for dose response</p>	<p>Solution: 10 mg/5 ml <i>Generic</i></p> <p>Tablet: 10 mg, 20 mg, 40 mg (scored) <i>Brand and generic</i></p>
Lexapro (escitalopram)	<p>Adults: MDD: 10mg PO once daily. MAX: 20mg <i>Dosing is also used for Generalized Anxiety Disorder (GAD)</i></p> <p>Geriatric (≥60 years): MDD: 10mg by mouth once daily</p>	<p>Headache Nausea Diarrhea Somnolence Insomnia</p> <p>BBW: same as above</p>	<p>Stop SSRI 14 days prior starting an MAOI (vice versa)</p> <p>Max: 10mg in pts. using CYP2C19 inhibitors (cimetidine, omeprazole)</p> <p>Allow 6-12 weeks after initiation for dose response</p>	<p>Solution: 5mg/5ml <i>Brand and generic</i></p> <p>Tablet: 5 mg, 10 mg, 20 mg (Brand scored) <i>Brand and generic</i></p>

Reviewed by: Dr. M. Pisano and Dr. M. Saud

CLINICAL

BACK TO COVER

CLINICAL

<p>Fluoxetine⁺ (Prozac)</p>	<p>Adults: Depression: 20 mg PO in the morning MAX: 80 mg/day</p> <p><i>Dosing also used for OCD</i></p> <p><i>Bulimia nervosa: 60mg/day</i></p> <p><i>Depression with bipolar I in combo Fluoxetine/Olanzapine [Symbyax]:20mg in the evening</i></p> <p><i>OCD: 20mg/day MAX: 80mg/day</i></p> <p><i>PMDD: Sarafem 20mg/day continuously or starting 14 days prior to menstruation an through the 1st day of menses</i></p> <p><i>Panic Disorder: Initial 10mg/day, up to 60mg/day</i></p> <p>Geriatrics: Initial dose-10mg/day</p>	<ul style="list-style-type: none"> • Insomnia • Nausea • Headache • Weakness • Diarrhea • Anxiety/ nervousness <p>BBW: same as above</p>	<p>Stop MAOI 14 days prior to start- ing an SSRI</p> <p>Stop fluoxetine 5 weeks prior to starting an MAOI.</p> <p>Allow 6-12 weeks after initiation for dose response</p>	<p>Solution: 20mg/5ml</p> <p>Sarafem tab: 10 mg, 20 mg</p> <p>Generic tab: 10 mg, 20 mg, 60 mg Capsule: 10 mg, 20 mg, 40 mg</p> <p>Prozac weekly: DR capsule: 90 mg per week</p>
<p>Paroxetine⁺ (Paxil)</p>	<p>MDD: Paxil, Pexeva 20 mg PO once in the morning MAX: 50mg/day</p> <p>Paxil CR: 25mg by mouth daily. MAX: 62.5mg/day</p> <p><i>Same dosing as GAD and OCD (max dose for OCD:60mg/day)</i></p> <p><i>Panic disorder: 10mg by mouth in the morning. MAX:60mg/day 12.5mg Paxil CR. MAX 75mg/day</i></p> <p><i>PMDD- 12.5mg in the morning</i></p> <p><i>PTSD: 20mg by mouth daily 12.5mg Paxil CR in the morning.</i></p> <p><i>PMDD: Brisdelle 7.5mg by mouth at bed- time</i></p> <p><i>Social Anxiety Disorder: 2mg/day</i></p> <p>Geriatric: 10mg/day MAX:40mg</p>	<ul style="list-style-type: none"> • Nausea • Ejaculatory disorder • Drowsiness • Insomnia • Weakness • Xerostomia • Decreased li- bido <p>BBW: Same as above</p>	<p>Stop SSRI 14 days prior starting an MAOI (vice versa)</p> <p>Allow 6-12 weeks after initiation for dose response</p> <p>Dose should be increased in one week intervals</p>	<p>Paxil Sus- pension: 10 mg/5 ml</p> <p>Paxil tab (HCl): 10 mg, 20 mg (Brand- scored), 30 mg,40 mg <i>Brand and generic</i></p> <p>Paxil CR (HCl): 12.5 mg, 25 mg, 37.5 mg <i>Brand and generic</i></p> <p>Brisdelle (mesylate): 7.5 mg</p> <p>Pexeva tab (mesylate): 10 mg, 20 mg (scored) 30 mg, 40mg</p>

Reviewed by: Dr. M. Pisano and Dr. M. Saad

<p>Sertraline[†] (Zoloft)</p>	<p>Adults: MDD/OCD: 50 mg by mouth daily. MAX: 200 mg/day. <i>Panic disorder/ PTSD/ social phobia: 25 mg/day by mouth daily for 1 week, then increase to 50 mg/day. MAX: 200 mg/day.</i></p> <p><i>PMDD: 50mg daily throughout menstrual cycle or during luteal phase</i></p>	<ul style="list-style-type: none"> • Nausea • Insomnia • Diarrhea • Headache • Dizziness • Xerostomia • Drowsiness <p>BBW: same as above</p>	<p>Stop MAOI 14 days prior to starting an SSRI (and vice versa).</p> <p>If somnolence is noted, administer at bedtime.</p> <p>Oral concentrate must be diluted immediately before use. <i>[Mix with 4oz (1/2 cup) of water, ginger ale, lemon/lime soda, lemonade, or orange juice only.]</i></p>	<p>Oral concentrate: 20 mg/ml <i>Brand and generic</i></p> <p>Tablets: 25 mg, 50 mg, 100 mg (all are scored) <i>Brand and generic</i></p>
<p>Fluvoxamine[†] (Luvox CR)</p> <p>*Available generically in IR tablets</p>	<p>Adults: OCD: 50mg/day at bedtime Max: 300mg/day</p>	<ul style="list-style-type: none"> • Nausea • Somnolence • Insomnia • Asthenia • Nervousness • Dyspepsia • abnormal ejaculation • Sweating • Anorexia <p>BBW: same as above</p>	<p>Stop MAOI 14 days prior to starting an SSRI (and vice versa).</p> <p>If somnolence is noted, administer at bedtime.</p> <p>Frail patients are at an increase risk for falling.</p>	<p>ER capsule: 100 MG, 150 MG <i>Brand</i> 100 MG, 150 MG; <i>Generic</i></p> <p>IR Tablet as maleate 25 mg, 50 mg, 100 mg <i>Generic</i></p>
<p>Vortioxetine[†] (Brintellix)</p>	<p>MDD: Initial 10mg by mouth once daily; may increase to 20mg daily</p> <p>For patients with low tolerability initiate: 5mg by mouth daily</p> <p>Maintenance. -5-20mg by mouth daily</p> <p>Dose adjustment for CYP2D6 poor metabolizers: 10 mg PO daily MAX: 10mg/day</p>	<ul style="list-style-type: none"> • Nausea, • Female and male sexual disorder • Dizziness • Abnormal dreams <p>BBW: same as above</p>	<p>Stop MAOI 14 days prior to initiating vortioxetine</p> <p>Stop Vortioxetine 21 days prior to initiation of an MAOI</p> <p>Upon discontinuation: doses \geq15mg should be decreased to 10mg/day for 1 week before full d/c to prevent withdrawal symptoms</p>	<p>Oral tablets: 5 mg, 10 mg, 20 mg <i>Brand only</i></p>

CLINICAL

Reviewed by: Dr. M. Pisano and Dr. M. Saad

Serotonin- Norepinephrine Reuptake Inhibitors

Name	Dosing	ADRS	Counseling/Info.	Strengths
Venlafaxine^{*†} (Effexor, Effexor XR)	<p>Adult: MDD/GAD:(IR) 75 mg/day by mouth in 2-3 divided doses; Max: 375 mg/day (3 divided doses). (ER) 37.5-75 mg/day by mouth daily. Max: 225 mg</p> <p><i>Social phobia: (ER) 75 mg by mouth daily.</i></p> <p><i>Panic disorder: (ER) 37.5 mg/day for 7 days; increase dose after 1 week to 75 mg/day; MAX: 225 mg/day.</i></p>	<ul style="list-style-type: none"> • Nausea • Headache • Somnolence • Dizziness • Insomnia • Xerostomia • Weakness • Elevated Blood Pressure 	<p>Stop MAOI 14 days prior to initiation of an SNRIs (vise versa)</p> <p>Alcohol will increase the effects of this medication</p> <p>Can cause increase in blood pressure</p> <p>May cause sustained increase in blood pressure or tachycardia. Control pre-existing hypertension prior to initiation of venlafaxine therapy.</p>	<p>Capsule ER 24 Hour: 37.5 mg, 75 mg, 150 mg Brand and Generic</p> <p>Tablet: 25 mg, 37.5 mg, 50 mg, 75 mg, 100 mg Generic</p> <p>Tablet ER 24 Hour: 37.5 mg, 75 mg, 150 mg, 225 mg Generic</p>
Desvenlafaxine[*] (Pristiq)	<p>MDD: 50mg by mouth daily</p> <p>Manufacturer states- no evidence that doses >50mg/day have additional benefit</p>	<ul style="list-style-type: none"> • Nausea • Xerostomia • Dizziness • Insomnia • Hyperhidrosis <p>BBW: Same as Above</p>	<p>Stop MAOI 14 days prior to initiation of an SNRIs</p> <p>Stop desvenlafaxine 7 days prior to initiation of an MAOI</p>	<p>ER tablet: 50 MG, 100 MG Brand and Generic</p>

Reviewed by: Dr. M. Pisano and Dr. M. Saad

CLINICAL

<p>Duloxetine* (Cymbalta)</p>	<p>MDD: Starting Dose: 20mg twice daily Max:120mg/day</p> <p><i>Diabetic peripheral neuropathy: 60mg/day</i></p> <p><i>Fibromyalgia: Starting Dose: 30mg/day Max: 60mg/day</i></p> <p><i>GAD: Starting Dose: 60mg/day Max: 120mg/day</i></p> <p><i>Chronic Musculoskeletal Pain: Starting Dose: 30mg/day Max: 60mg/day</i></p>	<ul style="list-style-type: none"> • Nausea • Xerostomia • Headache • Insomnia • Dizziness • Somnolence • Fatigue <p>BBW: Same as Above</p>	<p>Stop MAOI 14 days prior to initiation of duloxetine.</p> <p>Stop duloxetine 5-14 days prior to initiation of an MAOI.</p>	<p>DR Cap- sule: 20 mg, 30 mg, 60 mg <i>Brand and Generic</i></p>
<p>Levomilnacipran* (Fetzima)</p>	<p>MDD: Starting Dose: 20 mg once daily for 2 days; increase to 40 mg once daily; Maintenance: 40-120 mg once daily; Maximum: 120 mg daily</p>	<ul style="list-style-type: none"> • Nausea • Orthostatic hypotension • Constipation • Tachycardia <p>BBW: Same as above</p>	<p>Stop MAOI 14 days prior to initiation of levomilnacipran.</p> <p>Stop levomilnacipran 7 days prior to initiation of an MAOI intended to treat psychiatric disorders. * efficacy has not been established for longer than 8 weeks</p>	<p>ER Cap- sule: 20 mg, 40 MG <i>Brand and Generic</i></p> <p>ER Cap- sule: 80 mg, 120 mg <i>Brand</i></p>
<p>Milnacipran* (Savella)</p>	<p>Fibromyalgia: 50 mg twice daily.</p> <p>Titration schedule: 12.5 mg once on day 1, then 12.5 mg twice daily on days 2-3, 25 mg twice daily on days 4-7, then 50 mg twice daily thereafter. Dose may be increased to 100 mg twice daily, based on individual response. Doses >200 mg daily have not been studied.</p>	<ul style="list-style-type: none"> • Nausea • Headache • Constipation • Insomnia • Hot flashes • Inc BP <p>BBW: Same as above</p>	<p>Stop MAOI 14 days prior to initiation of milnacipran.</p> <p>Stop milnacipran ≥ 5 days prior to initiation of MAOI intended to treat psychiatric disorders.</p>	<p>Savella Ti- tration Pack: 12.5 & 25 & 50 mg (55 ea)</p> <p>Tablet:12.5 mg, 25 mg, 50 mg, 100 mg <i>Brand</i></p>

CLINICAL

Reviewed by: Dr. M. Pisano and Dr. M. Saad

Abbreviations	
BBW	Black box warning
CR	Controlled Release
DR	Delayed Release
ER	Extended Release
GAD	General anxiety disorder
IR	Immediate Release
MAOI	Monoamine oxidase inhibitor
MDD	Major depressive disorder
OCD	Obsessive compulsive disorder
PO	By Mouth
PMDD	Premenstrual dysphoric disorder
PTSD	Post Traumatic Stress Disorder
SNRI	Serotonin- Norepinephrine Reuptake Inhibitors
SSRI	Selective Serotonin Reuptake Inhibitors
Y/O	Years or older
*	Renal impairment, adjustment needed
†	Hepatic impairment, adjustment needed

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Reviewed by: Dr. M. Pisano and Dr. M. Saad

Drug Shortages: Effects & Costs in the United States Healthcare System

By: Valentina DiGangi, PharmD Candidate c/o 2017, Brandon Hu, PharmD Candidate c/o 2018, Sang Hyo Kim, Staff Editor, Samantha Lau, PharmD Candidate c/o 2018, and Seewoo Yoon, PharmD Candidate c/o 2018

What does a clinician do when there is limited access to a particular drug, such as morphine? Should they treat a patient who is suffering from extreme leg pain or should they save it for a future emergency? Such scenarios are what ambulance squads experience because of the drug shortage crisis in the United States.¹ Because of the diverse factors that lead to drug shortages, more government regulations are being implemented to improve communication amongst different parties that are involved. Some examples of include requiring the manufacturers to notify the FDA when there is a disruption in supply, or informing other manufacturers to increase production to compensate for the shortage.

Significance of Drug Shortages

It is shocking to see that a major problem like drug shortage exists in the United States, where drug treatment is more prevalent than anywhere else. Discuss-

Drug shortages are multi-factorial—some of them predictable while others are not—making it difficult to pinpoint an exact cause.

ing and searching for practical solutions to the drug shortage issue is important because the drugs that are scarce are “essential for treating most critical health conditions, and shortages in any of them inevitably [cause] disruptions in patient safety and quality of healthcare.”² Furthermore, this issue is becoming more crucial than ever before, since there has been a sharp increase in the rate of drug shortages (Figure 1).

Factors of Drug Shortages

Drug shortages are multi-factorial—some of them predictable while others are not—making it difficult to pinpoint an exact cause. According to the American Society of Health-System Pharmacists (ASHP) drug shortage program, the most common causes of shortages in 2011 included manufacturing problems, constituting 23%, supply/demand issues at 13%, and unknown causes at 55%.³ Drug Shortages

Federal officials attribute the delays of the drugs to the plants that make sterile injectable, which account for about 80% of the scarce medicines. Further, one third of the manufacturing capacity is not reached because of factory closures due to quality issues.¹ Some of the unpredictable factors include natural disasters, raw materials, non-compliance with regulatory standards, and voluntary recalls.⁴ Natural disasters such as floods, fires, and hurricanes affect drug product availability in the following ways: finished products become damaged, and in situations where there is only one producer, site damage to facilities result in long term shortages.³ Raw material is also another factor. A drug, for example, may rely specifically on one major raw material, which may be produced only by a sole-source supplier. In addition,

if there is a disruption in the chain of production of the material, problems arise, and multiple manufacturers of the drug are affected.⁵

When the FDA decides to stop manufacturer production because of quality control issues, practices shortages also occur; and reimbursement issues force the drugs to be set at such low prices that it discourages companies from making the drug.⁴ Private physicians are also affected because they have a shortage on drugs to refer the patients to. The shortages have even forced the FDA to release drugs which have been actually recalled in the past. For example, single dose vials of Sodium Thiosulfate, used for chemotherapy, contained glass particles. Under normal circumstances, these would have been recalled, but due to a shortage in the drug, healthcare professionals were informed to filter the drug before administering it to patients.¹

Economic Reasons for Drug Shortages

Manufacturing difficulties, supply and demand, business and economics, regulations, supply chain,

and healthcare systems all affect drug shortage. When a company shifts its resources from manufacturing to research or to the production of an alternative product, it results in loss of production, which may lead to layoffs.³ Drug supply is also affected by insufficient profits, introduction of generic alternatives, market shares, clinical demand, and mergers. These factors can cause permanent or temporary product reduction depending on the shift in production, delay in allocating new resources, or the time it takes to begin production in a new facility.

Supply and demand issues occur when drug demand increases beyond expectations or production capacity. For example, the responsiveness of prescription drug prices do not change drastically in either the short or the long run because these medically necessary drugs have few substitutes and are mostly purchased by consumers with pre-established rates through health insurance.⁵ Lastly, supply chain issues affect drug supply depending on the end users' decisions. Wholesalers or hospitals may have poor ordering practices, delivery delays, restrictive distribution methods, and methods of inventory based on increased cash flow resulting in drug shortages.³

Impact of Drug Shortages

Shortages occurring in the prescription drug and vaccine market can have a negative impact on both healthcare providers and patients. Shortages in drug supply lead to higher hospital expenses. A survey conducted in 2010 by Premier Healthcare Alliance found that drug shortages cost hospitals around \$200 million yearly due to having to resort to more expensive alternatives. There are also suppliers that buy up the remaining drug stock and try to sell it to hospitals at extremely high prices. A survey conducted by the ASHP estimated that yearly labor costs to manage shortages average to about \$216 million nationwide.⁵ Pharmacists also have to spend more hours dealing with drug shortages. They have to talk to manufacturers and keep their electronic databases up to date, which takes away time from providing direct patient care. Using alternatives for drugs in short supply can bring increased risk. Phar-

macists have to make sure there are no multi-drug interactions when giving alternatives to patients. Also, alternative drugs may have different side effects or may be less effective than what was originally prescribed. Prescribing alternative drugs may lead to medication errors such as wrong dosage. Some patients may need drugs urgently, but shortages in drug supply would lead to rationing to patients who "need it more." Another problem that comes with drug shortages is quality control. When there are shortages in drug supply, substitute medications may not live up to required standards. Hospitals or pharmacies may have to buy drugs from less reputable sources. And buyers are at increased risk of purchasing counterfeit drugs.

Strategies in Managing Drug Shortages

According to many experts and authorities including Scott M. Mark Pharm.D., M.S., from ASHP, the best solution to the drug shortage problem is to foster prompt communication among different levels of regulators, medical practitioners, and healthcare institutions, such as wholesalers, distributors, drug manufacturing companies, hospitals, pharmacies, and the FDA. It has been advised that all small and large organizations establish a department or nominate someone to supervise the drug distribution process and drug shortage situation.³ Several other strategies include validating drug shortages, assessing inventory of drugs in short supply, establishing contact with other health systems, identifying alternative drugs or therapeutic equivalents, determining primary patients to receive drugs in short supply, adjusting or reconstructing clinical guidelines and policies, and finally, developing timely communication systems and strategies.⁴ In addition to these possible solutions, it would also help if the FDA had more control in forecasting and preventing drug shortages so that it could terminate the gray market activities, the import and sale of goods by unauthorized dealers.²

In the Future

Although a higher number of potential drug shortages have been prevented in recent years, the

A survey conducted in 2010 by Premier Healthcare Alliance found that drug shortages cost hospitals around \$200 million yearly...

total number of existing drug shortages still continues to rise. Much more has to be done in order to ensure that these numbers decrease. In the long run, drug shortages can be predicted and prevented if the FDA not only has the ability to track which drugs are running low in supply, but also if it deciphers the patterns behind drug shortages. In order to do this, the FDA must be given more power to regulate the determinants leading up to drug shortages. Some problems that may be better managed include the following: a single production line producing too many drugs despite limited space, or manufacturers deciding not to produce certain drugs because they do not bring in sufficient profits.⁶ FDA can ensure that all drugs are being produced sufficiently. This will play a crucial role in preventing shortage of drugs as well as providing drug substitutes.

Although drugs that have higher demand warrant priority in terms of production and distribution, all drug shortages should be acknowledged and reported to the FDA. The FDA can then take appropriate actions to prioritize and address the shortages. When certain drugs are scarce due to manufacturing problems, the FDA should be able to hasten the drug review process for substitute drugs, as well as relax drug importation laws.⁴ These changes can be carried out in emergencies, such as during a shortage of high-demand drugs, because the medical needs and safety of the people must always be the first priority of the drug industry.

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OPINIONS

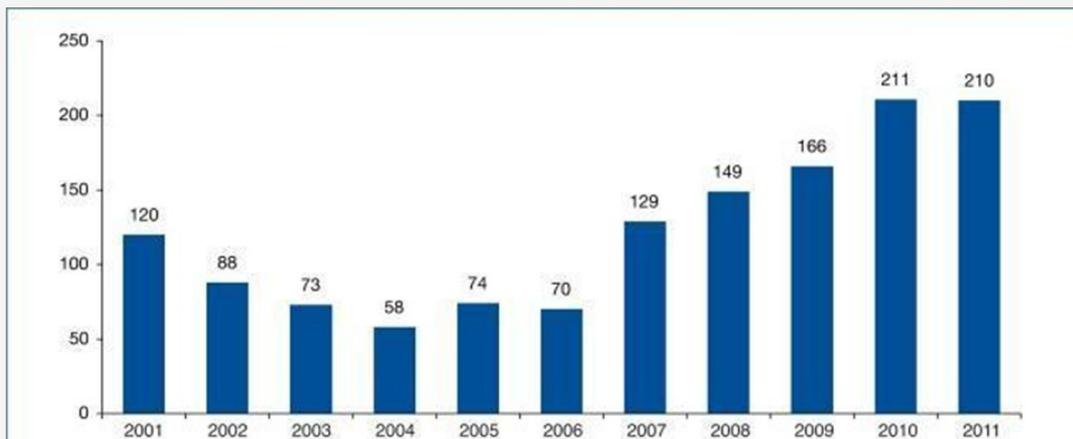


Figure 1 National drug shortages from January 2001 to September 15, 2011. Each column represents the number of new shortages identified during that year. (From Fox ER. University of Utah Drug Information Service.)

Source: Copyright © 2011, MediMedia USA, Inc. (Ventola, 2011)

Herbal Treatment Matching Puzzle

By Davidta Brown, Senior Staff Editor

Match the herbal treatment with the symptom or illness that it is used to alleviate or prevent. (Note: All herbals are paired only with symptoms that they are identified as "Possibly Effective" or "Likely Effective" to treat according to AccessPharmacy® Quick Reference: Herbs & Supplements.)





By: Sherine Jaison
PharmD Candidate
Class of 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?

Answers

Matching Column: Look-Alike Sound-Alikes

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. Used in the maintenance treatment of bronchospasm associated with COPD 2. A medication does not need any renal or hepatic adjustment and is used to treat hyperkalemia 3. Used to treat serum phosphate serums in patients with chronic kidney disease 4. An atypical antipsychotic that is not approved for children under the age of 10. 5. Some of the unlabeled indications for this medication include binge eating disorder, bulimia nervosa and generalized eating disorder 6. This medication should be administered in the evening for maximal efficacy 7. A DPP-IV inhibitor that can be administered without regard to meals 8. An antiviral associated with drug induced hepatotoxicity 9. Used for the treatment of tinea pedis, tinea cruris and tinea corporis 10. Used for prevention and treatment of infection in second and third degree burns | <ol style="list-style-type: none"> A. Sitagliptin B. Spiriva C. Sodium polystyrene sulfonate D. Sevalamer E. Sertraline F. Seroquel G. Simvastatin H. Silver sulfadiazine I. Selzentry J. Spectazole |
|---|--|

How Did You Do???

Answers to Crossword & Look Alike and Sound Alike

1.G 2.D 3.I 4.A 5.L 6.H 7.B 8.F 9.C 10.K 11.E 12.J

Quote of the Month

By: Melissa Roy, Co-Copy Editor [Graphics Focused]



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

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: TEAM MEMBERS



@ Katharine Cimmino (6th 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, 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 (6th 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 (5th 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.



@ Erica Dimitropoulos (6th Year, STJ; Co-Copy Editor [Content-Focused])

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!



@ Melissa Roy (6th Year, STJ; Co-Copy Editor [Graphics-Focused])

We as future healthcare professionals owe it to our patients and ourselves to be 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. Feel free to reach out to me with suggestions and comments.

EDITORS

RHO CHI POST: TEAM MEMBERS



@ Tamara Yunusova (4th Year, STJ; Senior Staff Editor)

My name is Tamara Yunusova, and I am a 3rd 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.



@Davidta Brown (4th Year, STJ; Senior Staff Editor)

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



@ Beatrisa Popovitz (6th Year, STJ; Senior 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.



@ Ada Seldin (6th 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 (3rd 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.



@ Fatema Elias (5th Year, STJ; Staff Editor)

I am honored to be a part of the Rho Chi Post team. In this age of technology and the continuously changing healthcare profession, I hope to engage like-minded students and professionals. Writing is something that I hold dear to my heart and I hope with this newsletter we can all stay well informed, interested, and educated.



@ Sherine Jaison (6th Year, STJ; Staff Writer)

I find the Rho Chi Post extremely informative and am eager to join the team. I hope my articles will enlighten you about the recent developments in the field of pharmacy and will help you to be a well-informed healthcare provider.



@ Azia Tariq (4th Year, STJ; Staff Writer)

The Rho Chi Post is a prominent and highly esteemed resource for pharmacy students and professionals. I am privileged to be a part of the team and hope to contribute informative and engaging pieces to the newsletter.



@ 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 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, faculty-approved publication that aims to promote the pharmacy profession through creativity and effective communication. Our publication is a profound platform for integrating ideas, opinions, and innovations from students, faculty, and administrators.

VISION

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

VALUES

Opportunity, Teamwork, Respect, Excellence

GOALS

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



Anthony, Tyler, Sara, Tasnima, Joshua, Fawad at the 2014 Induction Ceremony

President: **Tyler Valente**
 Vice President: **Fawad Piracha**
 Secretary: **Tasnima Nabi**
 Treasurer: **Anthony Nania**
 Historian: **Sara James**
 Media Relations Coordinator **Joshua Bliss**
 Faculty Advisor: **S. William Zito, PhD**

UPCOMING EVENTS

Sept 24-26: Health Connect Fall Hospital Pharmacy Conference
 Dallas, TX

Oct 12-15: ACCP Annual Meeting
 Austin, TX

Nov 10-14: AAPS Annual Meeting
 San Antonio, TX

Dec 7-11: ASHP Midyear
 Anaheim, CA