LA HEALTH-SYSTEM PHARMACIST

Newsletter of the Louisiana Society of Health-System Pharmacists

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FROM THE DESK OF THE PRESIDENT

On August 7th and 8th, LSHP convened our annual Strategic Planning Retreat and Board of Director's Meeting in Woodworth, LA. Attendance was low which was likely due to scheduling the retreat the week prior to school restarting, a prime vacation time. We will likely move the next meeting to the end of July or late August to be more convenient for the Board of Directors and Committee Chairs. I would personally like to thank each of you who attended, and for those who couldn't attend, thank you for communicating your input prior to the retreat. I would also like to congratulate our new Officers and Board -Members-At -Large.

- New officers
  Scott Dantonio, President-Elect
  Keturah Robinson, Immediate Past President
- New Board Members-At-Large
  Mike Loftin
  Helen Calmes
- Vacant Board Members-At-Large Seats that were filled
  Laurel Andrews
  Camtu Ho

Please join me in congratulating our new representatives. I am looking forward to a productive year.

Next I would like to share with you a few key points that were discussed at our retreat. The new committee Chairs and the Board liaisons for each committee were announced.

- Education and Workforce Development Chair:
  Shawn Manor (smanor@lsuhsc.edu)
  Board liaison: Roxie Stewart
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  Board liaison: Keturah Robinson
- Technician Activities Co-Chairs:
  Winona Thomas (winonathomascpht@aol.com) and
  Jonathan Bost (jbost@ochsner.org)
  Board liaison: David Loftin

Committee functions and responsibilities along with the LSHP Board of Directors Policy and Procedure Manual can be found on the LSHP website under the Board of Directors link. I encourage you to join a committee of your choice and actively participate. If you are interested in joining a committee please contact the committee Chair or myself. There's a lot of work to be done, your time and assistance will be welcomed and greatly appreciated.

The Board of Directors was charged with the following resolutions from the membership at the annual membership meeting. These where assigned to committees.

1. LSHP to form an ad hoc committee to work with ULM and Xavier to organize a Louisiana Social function to be held at the ASHP Midyear Clinical Meeting to be held in New Orleans in December 2011. It was decided that an ad hoc committee would be formed due to the size and

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SOUTHWEST-LSHP
VACANT

Announcing the LSHP Mid Year Meeting October 9 Sam's Town Shreveport

Register now!

Go to www.lshp.org/meet to register online or download a paper brochure!

The conference hotel is Sam's Town in Shreveport. Reservations may be made by calling (877) 429-0711.

See page 3 for the schedule of educational activities!

LSHP Bimonthly Newsletter LA HEALTH-SYSTEM PHARMACIST Publisher Information

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Copy, advertising and nonmember subscription inquiries should be directed to the Copy Editor, Kati Craig, at (225) 922-4520. Advertising rate sheets and deadlines are available upon request.

Please send article submissions to the newsletter editor, Dana Jamero, via email at djamero@xula.edu.

Make the Grade With These Continuing Pharmacy Education Sessions Offered at the Mid Year Meeting

Saturday, October 9, 2010

8:00-9:00 a.m.

Pharmacogenomics and Anticoagulation: FDA Supports the Use of Genetic Testing
Elizabeth Perry, PharmD *179-000-10-038-L04-P / 179-000-10-038-L04-T*
OR
Vaccines 101
Katie Barber, PharmD *179-000-10-039-L01-P / 179-000-10-039-L01-T*

9:00-10:00 a.m.

Chronic Myelogenous Leukemia *204-000-10-426-L01-P*
Ashley Engemman, PharmD, BCOP
OR
An Evaluation of the Use of Erythropoietin Stimulating Agents in Oncology Patients
Elizabeth Morgan, PharmD *179-000-10-040-L01-P / 179-000-10-040-L01-T*

10:00-11:00 a.m.

The Continuing Struggle for Compliance with USP <797>
Loretta Lemoine, PharmD *179-000-10-041-L03-P / 179-000-10-041-L03-T*

11:00 a.m.-12:00 p.m.

Exhibits

12:00-1:00 p.m.

Lunch with Exhibitors

1:00-2:00 p.m.

Clinical Controversies and Updates in Diabetes
Jamie Terrell, PharmD *179-000-10-042-L01-P*
OR
Polymyositis
Mia Ajekwu Bassaragh, PharmD *179-000-10-043-L01-P / 179-000-10-043-L01-T*

2:00-3:00 p.m.

Acetaminophen Toxicity
Shawn Manor, PharmD *179-000-10-044-L01-P*
OR
Pulmonary Hypertension
Hui Jamie Yun, PharmD *179-000-10-045-L01-P / 179-000-10-045-L01-T*

3:00-4:00 p.m.

Therapeutic Management of Asthma in Children
Chau Nguyen, PharmD *179-000-10-046-L01-P*
OR
An Overview of Targeted Therapy in Advanced Renal Cell Carcinoma
Jeremy Taylor, PharmD *179-000-10-047-L01-P / 179-000-10-047-L01-T*

4:00-5:00 p.m.

HIV Treatment and Associated Metabolic Abnormalities
Karlye Pesci, PharmD *179-000-10-048-L02-P / 179-000-10-048-L02-T*

LSHP Welcomes *Disney Institute* to Baton Rouge on September 28, 2010

Every hospital, clinic, group medical practice, dental practice, or freestanding medical care provider has the opportunity to distinguish themselves through the delivery of quality services.

A one-day local workshop, **Disney's Approach to Quality Service for Healthcare Professionals** program will show you the importance of attention to detail in everything Disney does -- from training its Cast Members (employees) to treating every Guest (patient) as a VIP. You will hear the stories and see how Disney best practices can be easily adapted to your healthcare delivery organization.

Professional development doesn't cost—it pays. It pays by creating a framework of focused energy in a vacuum of uncertainty. It pays by helping an organization gain share in a slow economy. The long-standing reputation Disney Destinations has for incredible service and friendly employees is not magic, it is sound ideology consistently applied in business. This program is designed to help Healthcare Professionals improve their organization's quality service by immersing themselves in the successful Disney model.

IMPORTANT: Please use the Louisiana Society of Health-Systems Pharmacists promotional code **LSHPMNE** to receive **$50 OFF PER GUEST** when registering. Additional group discounts are available.

TO LEARN MORE AND REGISTER GO TO:
www.KeysBatonRougeLA.com
No prerequisite training required.

Continued from ***President*** *page 1*

complexity of this task. Keturah Robinson will be heading this ad hoc committee in coordination with our ULM faculty Board members. This will be a huge task on a short time line so please extend any assistance you can to Keturah. We will need to know if ULM and Xavier are interested and a projected budget amount by our October budget meeting.

2. LSHP to work with manufacturers to develop standard barcodes and NDC numbers. This is also a huge task. One that I am not sure a state organization can accomplish. Our plan is to work closely with ASHP on this goal. Two committees will work jointly on this resolution, Pharmacy Practice and Pharmacy Management.
3. LSHP to consider technicians as full members of the society with voting rights. This was assigned to Organizational Affairs. Organizational Affairs is a committee of the executive officers of the Board of Directors whose responsibility is all issues of a procedural nature and management of the bylaws and governing documents.
4. LSHP to consider adding a technician to the board of directors. This resolution was also assigned to Organizational Affairs for discussion and decision.
5. LSHP to review the current systems, position statements, etc. regarding information management and off site order entry as it relates to Louisiana pharmacists and report to the general membership. This was assigned to Public Policy. We have charged them to keep the organization up to date on this quickly changing area through updates in the bimonthly newsletter. Keep a close lookout for these updates in upcoming editions.
6. LSHP to advocate for bar code labeling on packaging going to patient's bedside and how it relates to patient safety and not just inventory control. As with the other barcoding resolution, this is a big goal for a state organization. This was assigned to Pharmacy Practice and Pharmacy Management. They will work on this and keep us all apprised of developments.
7. For LSHP to work toward a Louisiana coalition of Emergency Medical Response in the international arena. This was tabled until the October meeting because we needed clarification from the author of the resolution.

Again if you are interested in helping out with any committee, please contact the Chair or myself to volunteer.

Lastly, we are only a few weeks away from our fabulous Midyear meeting in Shreveport. All of you should have received an email about online registration. If you have not, you can find a program schedule and registration link on our website. The meeting will be at Sam's Town in Shreveport during the Red River Revel. The Board of Directors meeting will take place on Friday, October 8th followed by the Welcome Reception and Festival later that evening. The actual meeting, exhibit and lunch will be on Saturday, October 9th. This year's meeting will offer about 13 hours of continuing education opportunities for pharmacists and technicians; a maximum of 7 hours per individual. If there are any particular issues that you would like brought to the Board's attention, please email myself or a board member prior to the meeting. I hope to see you soon at the October 9th meeting.

Teresa Nash
LSHP President

Northeast Chapter Update

By: Jessica Brady, PharmD, BCPS
Northeast Chapter President

The Northeast Chapter has several fall meetings planned jointly with the 5th District Pharmacists Association. These will include continuing education programs entitled "*Chronic Non-Cancer Pain Management*" on September 16th presented by Adam Pate, PharmD, "*Management of the Cirrhotic Patient*" on October 21st presented by Kristen Pate, PharmD, and "*HIV Management Update*" on November 18th presented by David Caldwell, PharmD, AAHIVE. We welcome our new members and hope to see increased attendance at all meetings. NELSHP also congratulates our ULM Student LSHP Chapter for continued recognition as an ASHP Student Society of Health-System Pharmacists.

Xavier Student Chapter Update

By: Mia Incaprera
Xavier Student Chapter President

As our new academic year begins, the Xavier chapter of LSHP has already put a lot of work in. The summer began with a 1st place achievement at the state convention for our chapter's poster project! The poster detailed our yearlong project on the Influenza and H1N1 viruses. With much help from our faculty, especially Dr. Amne Borghol and Dr. Camtu Ho, the poster was presented by Maxwell Haslauer and myself, Mia Incaprera. We are now planning on how to expand this project to further educate our student body and the communities around us.

Although this year has just begun we already have many events and speakers planned. Following the organizational fair for the college in the next few weeks, our chapter will kick off with our first meeting, "What is LSHP?", designed to inform the incoming P1s about the organization and get our colleagues excited about the options our profession has to offer. We also have many community services in the works ranging from walks to support various causes to screenings to promote health.

As a recognized ASHP Student Societies of Health-system Pharmacy (SSHP) chapter, our clinical skills competition was a success. The winners will be announced soon and they will be on their way to Anaheim, CA for the midyear meeting to represent Xavier at the national level. Thanks to all who participated and judged!

The Xavier chapter looks forward to a bountiful year. Good luck to all students, faculty, and advisors in the 2010-2011 school year.

LSHP ULM Student Chapter Update

By: Julie Sheridan
ULM Student Chapter President

Well the semester is getting off to a wonderful start at the ULM College of Pharmacy. I have met with the executive team, as introduced in the previous newsletter, to plan the semester. We will hold our first general meeting for students on September 7, 2010. At the meeting, we plan to discuss all the future events. We are looking forward to the Midyear meeting and hosting our Clinical Skills Competition. We are even planning to have our fundraiser ready for Mid-year. Our fleur-de-pharm will be featured on a sweatshirt type blanket. Also, we will be selling another shirt this year with the fleur de pharm. I cannot wait for you to see a preview at the meeting. The blankets are really going to be nice!

The executive committee has determined the professional developments that LSHP will offer this semester to maintain our Student Societies of Health-system Pharmacy (SSHP) recognition. We will be discussing topics of pharmacy licensure with Dr. Jeffrey Evans and poison prevention. In the spring, we will discuss residencies and will carry out our service project. We are planning on going out to various high schools in the Monroe area and promoting the profession of pharmacy. We will support this with information about health-system pharmacy. I think this will really foster a sense of pride in our chapter members and enhance their leadership skills.

Mark your calendars!

National Pharmacy Week is October 17-23, 2010.

C1 Esterase Inhibitors for the Treatment of Hereditary Angioedema

By: Kieu D. Nguyen, PharmD

Hereditary Angioedema (HAE) is a very rare and potentially life threatening genetic condition that occurs in about 1 in every 10,000 to 50,000 people. HAE most commonly presents as marked swelling of the face, mouth and/or airway that occurs spontaneously or to minimal triggers (such as mild trauma). Swelling can occur in any part of the body. Although the events that induce attacks of angioedema in HAE patients are not well defined, it is thought that activation of the contact system causes increased vascular permeability and the clinical manifestation of HAE attacks. Low levels of C1 esterase inhibitor are found in patients with HAE Type I, accounting for 80-85% of cases. HAE Type II is responsible for 10-15% of cases in which the protein circulates in normal amounts but is dysfunctional.[1]

C1 esterase inhibitor is a normal constituent of human blood. Its primary function is to inhibit the activation of the complement, contact, and fibrinolytic systems. Of particular concern is the release of bradykinin, a vasoactive peptide that causes blood vessels to dilate and increases vascular permeability, when the contact system is activated. Suppression of the contact system by C1 inhibitor is thought to modulate vascular permeability by preventing the generation of bradykinin.[1,2]

In patients with HAE, administration of C1 esterase inhibitor replaces the missing or malfunctioning protein in patients. Cinryze™ has an FDA-approved indication for routine prophylaxis against angioedema attacks in adolescent and adult patients with HAE, while Berinert™ is indicated for the treatment of acute abdominal or facial attacks of HAE in adult and adolescent patients.[1,2]

Cinryze™ Clinical Data

A randomized, double-blind and placebo controlled cross-over study evaluated whether Cinryze™ decreases the number of HAE attacks compared to placebo as determined by the number of attacks during a 12 week period in 22 patients. To be included patients had to have a diagnosis of HAE and a history of at least two HAE attacks per month. Patients were either randomized into a group receiving prophylaxis with Cinryze™ for 12 weeks followed by placebo for 12 weeks or a group receiving placebo first and then prophylaxis with Cinryze™. While receiving Cinryze™ prophylaxis, patients had a 66% reduction in days of swelling ($p<0.0001$), decreases in the average severity of attacks ($p=0.0006$), and decreases in the average duration of attacks ($p=0.0023$). The most common adverse reactions observed by ≥ 5% of the subjects after receiving Cinryze™ were upper respiratory tract infection, sinusitis, rash, and headache. There were no treatment-emergent serious adverse reactions.[4]

Berinert™ Clinical Data

One hundred and twenty four patients were included in a placebo-controlled double-blind prospective multinational randomized dose-finding study evaluating (1) whether Berinert™ shortens the time to onset of relief of symptoms of HAE attacks compared to placebo and (2) the efficacy of two different Berinert™ doses. To be included patients had to be experiencing an acute moderate to severe abdominal or facial HAE attack. The age range of patients included in the study was 6 to 72 years of age. Group randomization and results are as follows:

- Group A: 10 unit/kg (N=39)
- Group B: 20 unit/kg (N=43)
- Group C: Placebo (N=42)

Group A had a non-statistically significant difference in the time to onset of relief of symptoms compared to placebo. Group B experienced a significant reduction in time to onset of symptom relief compared to placebo ($p=0.0016$) with a median of 48 minutes and >4 hours, respectively. At <60 minutes after administration, 62.8% of patients in Group B experienced an onset of relief compared to 26.2% in the placebo group. The most common adverse reactions observed by ≥4% of subjects after Berinert™ treatment were subsequent HAE attack, headache, abdominal pain, nausea, muscle spasm, pain, diarrhea and vomiting. The most serious adverse reaction reported was an increase in the severity of pain associated with

	Cinryze™ by ViroPharma[3,4]	**Berinert™** by CSL Behring[3,5]
Dosage	Administer reconstituted solution of 1,000 units intravenously every three to four days at a rate of 1mL/min (10 min).	Administer 20 units/kg intravenously for acute abdominal or facial attacks of HAE at a rate of approximately 4 mL/min.
Half-life	Adults: 56 hours	Adults: 18.5 hours
Special Populations	• Pregnancy C • Studies have not been conducted to evaluate the pharmacokinetics in special patient populations identified by gender, race, geriatric age, or the presence of renal or hepatic impairment	
Interactions	No drug interaction studies have been conducted	
Precautions & Contra-indications	• Hypersensitivity reactions may occur • Thrombotic events have occurred in patients receiving off-label high dose C1 esterase inhibitor therapy • Manufactured from human plasma and may contain infectious agents • Do not use in patients with a history of life-threatening immediate hypersensitivity reactions, including anaphylaxis, to C1 esterase inhibitor preparations	

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Prolia™ (denosumab): A New Treatment for Osteoporosis

By: Fahamina Ahmed, PharmD

Osteoporosis is often called the silent disease because many people don't know they have it. People are often diagnosed after they have suffered a fractured hip or vertebra due to a fall. According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, one out of every two women and one out of every four men over the age of 50 will fracture a bone in their life time due to osteoporosis.

Osteoporosis, which literally means "porous bones", develops when bone resorption exceeds bone formation. Oral bisphosphonates are usually first-line therapy chosen due to their low cost and high efficacy profile in increasing bone mineral density and decreasing osteoporotic fractures. As of June 1, 2010, a new option for the treatment of osteoporosis has become available. The FDA has approved Prolia ™ (denosumab), the first monoclonal antibody that inhibits receptor activator of nuclear factor kappa-B ligand (RANKL). RANKL binds to RANK on the surface of osteoclasts to break down bone. Denosumab inhibits RANKL binding and thus inhibits osteoclast formation and activity which results in decreasing bone resorption. Denosumab has been approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture, patients with osteoporosis for whom other osteoporosis treatments have failed, and patients who cannot tolerate other osteoporosis treatments. The efficacy and safety of denosumab was demonstrated in a three year randomized, placebo-controlled trial called Fracture Reduction Evaluation of Denosumab in Osteoporosis Every 6 Months (FREEDOM). The trial involved 7,808 postmenopausal women with osteoporosis and demonstrated that 60mg of denosumab compared to placebo resulted in a reduction of 68% in vertebral fractures, 40% in hip fractures, and 20% in non-vertebral fractures. Furthermore, compared to placebo, after three years denosumab was associated with increased bone mineral density by 9.2% at the lumbar spine and 6.0% at the total hip.

A phase 3 international, double-blind, 12 month study involving 1,289 postmenopausal women was conducted to study the safety and efficacy of denosumab compared to oral alendronate. The women received 60 mg subcutaneous injections of denosumab every 6 months along with an oral placebo weekly, or 70 mg oral alendronate (Fosamax®) weekly along with placebo subcutaneous injections. After 12 months, bone mineral density at the hip increased by 3.5% in the denosumab group versus 2.6% in the alendronate group. Additionally, denosumab treatment resulted in increased bone mineral density by 0.6% at the femoral neck, 1.0% at the trochanter, 1.1% at the lumbar spine, 0.65% at the one-third radius when compared to alendronate. The study concluded that while the safety and incidence of adverse events were similar, the denosumab group had a greater increase in bone mineral density and decrease in bone turnover markers when compared to the alendronate group. Although clinical trials have been conducted comparing denosumab to oral bisphosphonates, clinical trials comparing the efficacy of denosumab to an intravenous form of bisphosphonates, such as zoledronic acid, are limited.

Denosumab is administered as a 60 mg subcutaneous injection twice a year. Patients are advised to take 1000 mg of calcium daily and 400 IU of vitamin D daily. Denosumab usage is contraindicated in patients with hypocalcemia. Once hypolcalcemia is corrected, treatment with denosumab may be initiated. The most common adverse reactions include back pain, pain in extremities, hypercholesterolemia, musculoskeletal pain, and cystitis. In the FREEDOM trial, more women using denosumab compared to placebo were hospitalized due to serious skin infections. Monitoring for signs of serious infection is advised. Dermatological reactions, such as dermatitis, rashes, and eczema, have occurred more commonly in women using denosumab compared to placebo. Denosumab should be discontinued if severe symptoms occur. Osteonecrosis of the jaw (ONJ) has been reported in patients that have used denosumab; therefore, a dental exam should be performed before initiating denosumab in patients with risk factors for ONJ. It is also recommended to keep good oral hygiene and inform the dentist about denosumab usage before dental procedures are performed. Furthermore, significant suppression of bone turnover has been evidenced during clinical trials. The long-term consequences with treatment are unknown.

Due to the uncertainty of the effect of prolonged use of the drug, the makers of Prolia™, Amgen, have established a post -marketing surveillance program to monitor more than 4,500 women already taking the drug for ten years. In addition, the company has set up a "risk evaluation and mitigation strategy" (REMS) program which consists of a medication guide explaining risks associated with Prolia™ to patients and a communication strategy for health care providers.

Intravenous forms for treatment of osteoporosis are options for women who cannot tolerate oral bisphosphonates, who have failed other treatments, or cannot adhere to the dosing regimen. Zoledronic acid (Reclast®) is a once yearly intravenous bisphosphonate that has been used as an option for these women. The approval of Prolia™ (denosumab) offers a new intravenous treatment option with a different mechanism of action than bisphosphonates. Although future clinical research and monitoring is necessary to establish the safety and efficacy of denosumab, the inhibition of RANKL offers a promising treatment in suppressing bone resorption for not only osteoporosis, but other indications for diseases caused by increased bone loss such as rheumatoid arthritis and cancer.

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*Continued from **C1** page 6*

HAE. Treatment-emergent serious adverse reactions (N=5) include laryngeal edema, facial attack with laryngeal edema, swelling, exacerbation of HAE, and laryngospasm. [5]

Conclusion

Data from these two studies support the use of C1 esterase inhibitor for prophylaxis and acute treatment of HAE, though data is limited due to the difficulties in recruiting an adequate number of participants as well as completing analyses based on HAE Type I or II. However, treatment with CI esterase inhibitor concentrate is currently considered the standard of care in many countries for the treatment of HAE, as several studies have found that therapy is an effective treatment for attacks and may lead to reduced frequency of acute HAE attacks, fewer hospitalizations and significant improvements in quality of life.[6]

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