



# LA HEALTH-SYSTEM PHARMACIST

## Newsletter of the Louisiana Society of Health-System Pharmacists

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[www.lshp.org](http://www.lshp.org)

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### FROM THE DESK OF THE PRESIDENT

I am pleased to pinch hit for our President, Barries Leung, who has been out of town due to some pressing family issues. Barries had notified me two weeks ago that I would be joining his team this year as President-elect. I am delighted to begin serving the society and look forward to working with the membership over the next few years.

Due to a variety of logistical issues, the LSHP strategic planning retreat and Board of Directors meeting scheduled for July 14<sup>th</sup> and 15<sup>th</sup> in downtown Woodworth was cancelled. It will be rescheduled for late summer. Regardless, I have a number of issues to cover, and we will leave strategic planning topics for Barries to cover upon his return.

The most noteworthy pharmacy news in Louisiana is that the regulations governing collaborative practice between pharmacists and physicians were published in the *Louisiana Register* Vol. 33, No. 06 June 20, 2007 page 1124+ . Internet site: (<http://www.doa.louisiana.gov/osr/reg/0706/0706rul.pdf>). It is my understanding that it has been promulgated under Title 46 Part LIII Pharmacists of the *Louisiana Annotated Code* (LAC). Many thanks are in order to the multitudes of groups and individuals who brought these regulations to passage. Included among these are the Louisiana Board of Pharmacy, Mr. Malcolm Broussard our Executive Director of the Louisiana Board of Pharmacy (LBP), the Louisiana State Board of Medical Examiners (LSBME), the Louisiana State Medical Society, the Louisiana Pharmacists Association (LPA), Louisiana Independent Pharmacists Association (LIPA), LSHP (particularly Dr. Christopher Betz), Mr. Carl Aron, Mr. Morris Rabb, Mr. Ray Ford, Dr. Donald K. Hammett, Glenwood Regional Medical Center, and Dr. William Bourn. If someone or some group has been omitted, it is unintentional and I apologize.

I visited Aron's Pharmacy to offer my personal thanks to our Board President, Mr. Carl Aron for the LBP's perseverance and achievement in securing collaborative practice rights with physicians in the state of Louisiana. Mr. Aron was quick to inform me that we will not be able to rest on our laurel for long. The next step, which I firmly believe needs to involve LSHP members, committees, and officers has to do with insuring that

pharmacists who embark in the area of collaborative practice with physicians provide expert and responsible care to patients that reflects positively on our profession. We will have to earn this responsibility and trust with each and every patient visit and consultation in which we undertake.

It is my feeling that LSHP will have a unique opportunity to work with LPA, LIPA, and the LBP to help establish the guidelines and protocols for establishing collaborative practice in the areas of anticoagulation, asthma, diabetes, dyslipidemia, smoking cessation, and immunization against contagious disease. We are blessed in having two outstanding colleges of pharmacy in the state that have each taken a proactive role in promoting improved patient health care outcomes from pharmaceutical care. We have two excellent clinical division heads in Dr. William Kirchain and Dr. Charles Jastram from Xavier and ULM respectively. They along with their pharmacy practice faculties offer the Society and the profession of pharmacy in the state of Louisiana a host of opportunities for expanding our role in health care and improving the health of the citizens in our state.

In closing, I urge to you attend the Midyear Meeting of LSHP scheduled for October 5<sup>th</sup> and 6<sup>th</sup> in Shreveport. Whether you are a pharmacy technician, a student, a resident, or a pharmacist, it promises to be a lively program with items of interest to all. I look forward to seeing you there.

Marty Steffenson, Pharm.D,  
President-Elect



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## 2007 LSHP Election Results

Congratulations to the following  
LSHP Members who were elected  
to the 2007-2008  
LSHP Board of directors

**President:**

Martin Steffenson, PharmD

**Board Member:**

Iman Borghol, PharmD

Laurel Rodden, PharmD

**ASHP's Summer Meeting was  
June 24-27 in San Francisco, CA.  
The ASHP House of Delegates met  
and took action on a broad range of  
issues. To view the press release  
describing the new policies, visit**

**[http://www.ashp.org/s\\_ashp/  
article\\_press.asp?  
CID=168&DID=2037&id=21121](http://www.ashp.org/s_ashp/article_press.asp?CID=168&DID=2037&id=21121)**

**Miss out on San Francisco?  
Mark your calendar for the  
ASHP Midyear  
Clinical Meeting & Expo  
Dec. 2-6, 2007**

**Venetian Hotel & Sands Expo Center  
Las Vegas, NV**

**LSHP Bimonthly Newsletter****LA HEALTH-SYSTEM PHARMACIST****Publisher Information**

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Please send article submissions to the newsletter editor, Dana Jamero, via email at [djamero@xula.edu](mailto:djamero@xula.edu).

## Louisiana Collaborative Practice Agreement

Randy James Mire, Pharm. D.

Steven T. Boyd, Pharm. D., BCPS, CDE

Michael Jefferey Macaluso, Pharm. D

William Kirchain, Pharm. D., CDE

Pharmacists are expanding their roles in the community. Collaborative drug therapy management (CDTM) is the joint management of treatment involving a physician and a pharmacist to achieve the best possible outcome for the patient. Although informally practiced in the United States since pre-revolutionary days, formal CDTM agreements originated in the late 1800's. Contemporary, post-Durham-Humphrey Act CDTM agreements were first practiced at Indian Health Service Hospitals and Clinics in the early 1970's. As of 1999, 24 states allow some type of collaborative practice agreements in which physicians delegate patient management responsibilities to pharmacists. Currently more than 40 states allow collaborative practice agreements. The responsibilities range from refill approvals to modification or initiation of patient medication regimens.<sup>1</sup> In response to a directive from the Legislature, the Louisiana Board of Medical Examiners and the Louisiana Board of Pharmacy have recently drafted rules on collaborative drug therapy management. The rules define collaborative drug therapy management as the practice in which a pharmacist voluntarily agrees with a physician registered with the Louisiana State Board of Medical Examiners, to manage the disease specific drug therapy of one or more patients of such physician, within a predetermined range of medications selected by the physician and set forth in a written protocol.<sup>3</sup>

Collaborative drug therapy management is designed to promote health; prevent disease; and assess, monitor, initiate and modify medication use to assure that drug therapy regimens are safe and effective.<sup>2</sup> As part of the Louisiana collaborative drug therapy management agreement, the pharmacist will focus on a specific drug or drugs prescribed by a physician for a specific patient of such physician generally accepted within the standard of care for treatment of one of the following diseases or conditions listed in Table 1. Other drugs, diseases, or conditions may be recommended by an advisory committee to be appointed by the Louisiana Board of Medical Examiners. If a pharmacist and a physician want to establish a protocol for the disease specific medication management of a disease or condition not listed in Table 1, they can submit it for approval to the advisory committee once it is established.

The collaborative drug therapy management agreement is a written document in which a pharmacist and physician identify the terms and conditions under which they voluntarily

agree to participate in collaborative drug therapy management. No pharmacist shall engage in collaborative drug therapy management in Louisiana until registered with the Board of Pharmacy and granted the right to participate in such activity.<sup>3</sup> To be eligible for registration, a pharmacist shall, as of the date of application: possess a current, unrestricted license to practice pharmacy and be actively engaged in the practice of pharmacy in this state with a focus on the care similar to the activities anticipated in the collaborative drug therapy management agreement.<sup>3</sup> A pharmacist shall be deemed ineligible for registration of collaborative drug therapy management whose license is not in good standing. The application for registration to engage in collaborative drug therapy management will be made available by the Louisiana Board of Pharmacy. Registration of authority to engage in collaborative drug therapy management shall expire annually on the same day as a pharmacist's license unless renewed by the pharmacist with the appropriate forms.

Collaborative drug therapy management in Louisiana involves the pharmacist to assist physicians and improve the quality of patient care by providing patient-specific drug therapy. Due to the restructuring of the pharmacy degree to the doctor of pharmacy years ago and the implementation of pharmacy residency programs, many practicing pharmacists today obtain the skills necessary to utilize drug therapy to optimize patient-specific disease states. Collaborative drug therapy management allows the physician to have a qualified health care professional (i.e. the pharmacist) include their expertise to focus on patient-specific details, monitor drug therapy, manage financial aspects of patient care, and provide education to the physician and patients on drug therapy. Therefore, including the pharmacist in an ambulatory care setting restructures the responsibilities to care for patients and allows the physician the opportunity to improve the service offered. Consequently, the physician and the pharmacist may focus on the particular area of patient care in which they were trained to efficiently utilize their skills necessary to provide the best patient care. It is the opinion of these authors that implementing collaborative practice unites health care professionals in such a way that the strengths from each professional are distributed to reduce mistakes, optimize patient specific care, and save health care dollars. We encourage you to embrace this new legislature and consider developing a relationship with one of your physicians.

**Table 1**

Treatment and prevention of dyslipidemia
Treatment and prevention of diabetes
Smoking cessation therapy
Adjustment of medication administered by inhalant for treatment of asthma
Administration of disease specific vaccines to patients 16 years of age or older
Treatment and prevention of arterial and venous clot propagation and disease, i.e. anti-coagulation therapy

## Alli™ (orlistat)

By Brittany Bilello, Pharm.D.

Alli™ (orlistat) is the first FDA approved over-the-counter weight loss aid. It was FDA approved on February 7, 2007 and is currently available in stores nationwide. Alli™ is available as 60mg capsules, half the strength of Xenical® (orlistat) that is only available with a prescription. Alli™ is indicated for weight loss in adults, 18 years of age or older, who are obese. Alli™ should be used in addition to a reduced-calorie, low-fat diet and exercise program until the patient's goal weight has been achieved. Most weight loss will occur during the first six months of using Alli™. The recommended dose of Alli™ is one 60 mg capsule with each meal containing fat, not to exceed 3 capsules a day. It is important to instruct patients to take a multivitamin every night at bedtime since it has been shown that orlistat may reduce the absorption of fat-soluble vitamins.

Orlistat is a reversible inhibitor of gastric and pancreatic lipases. It is therapeutically active in the lumen of the stomach and small intestine where it forms a covalent bond with active serine residue sites of gastric and pancreatic lipases. As a result, the inactivated enzymes are no longer able to hydrolyze dietary fat (triglycerides) into absorbable free fatty acids and monoglycerides. Since triglycerides are not being absorbed, caloric intake decreases and may positively effect weight control.

There is minimal systemic absorption of orlistat; therefore, studies in special populations (geriatric, renal/hepatic insufficiency) were not performed. Caution is advised against using Alli™ with cyclosporin due to changes in cyclosporin absorption with variations in dietary intake. A possible interaction with Alli™ and warfarin may exist due to the potential for vitamin K levels to decrease while taking Alli™. The use of orlistat is contraindicated in patients with chronic malabsorption syndrome, cholestasis, or hypersensitivity to orlistat or any inactive components. Adverse events seen with Alli™ mainly pertain to bowel changes such as steatorrhea, and loose, frequent stools. These problems may be managed by eating a low-fat diet.

A multicenter, 16 week, randomized, double-blind,

placebo-controlled study was conducted at 20 US centers and involved 391 overweight subjects. The objective of the study was to determine the efficacy and safety of orlistat 60 mg, given 3 times a day, for weight loss in individuals who were mildly to moderately overweight. At the conclusion of the study, patients who received orlistat 60 mg lost significantly more weight than patients who received placebo (3.05 vs. 1.90 kg;  $p < 0.001$ , intent-to-treat analysis). Patients receiving orlistat 60mg lost 4.8 +/- 0.35% of baseline weight compared with 3.1 +/- 0.38% for the placebo group. Subjects receiving orlistat also had a greater relative reduction in total and low-density lipoprotein cholesterol, and both diastolic and systolic blood pressure. Both the orlistat and placebo groups had a similar safety profile; however, gastrointestinal events were significantly more prevalent in the group receiving orlistat.

According to the previous study, Alli™ has shown to be a useful addition to lifestyle changes and may significantly help overweight individuals lose weight and improve weight-related risk factors.

### References:

Anderson, JW, Schwartz Sm, Hauptman J, Boldrin M, Rossi M, Bansal V, Hale CA. "Low-dose orlistat effects on body weight of mildly to moderately overweight individuals: a 16 week, double-blind, placebo-controlled trial." The Annals of Pharmacotherapy 40, 1029 Aug 2006 1717-23. 27 Mar 2007 <<http://www.theannals.com/cgi/content/abstract/40/10/1717>>.

"Orlistat OTC (marketed as Alli) Information." U.S. Food and Drug Administration Center for Drug Evaluation and Research. 12 Feb 2007. FDA. 26 Mar 2007 <[http://www.fda.gov/cder/drug/infopage/orlistat\\_otc/index.htm](http://www.fda.gov/cder/drug/infopage/orlistat_otc/index.htm)>.

"Orlistat." Facts & Comparisons 4.0. 2007. 26 Mar 2007 <<http://www.factsandcomparisons.com/>>.

## The ASHP Council on Education and Workforce is soliciting your ideas!

The Council on Education and Workforce Development is concerned with ASHP professional policies related to the quality and quantity of pharmacy practitioners in hospitals and health-systems. Within the Council's purview are: (1) student education, (2) postgraduate education and training, (3) specialization, (4) assessment and maintenance of competence, (5) credentialing, (6) balance between workforce supply and demand, (7) development of technicians, and (8) related matters. Policy recommendations from this council this year dealt with issues such as Pharmacy Technician Training, Image of and Career Opportunities for Hospital and Health System Pharmacists, and Residency Programs.

If you have any ideas for topics that you feel are important to our profession and that you would like to have submitted as agenda items, please email Michael Cockerham at [mcocke@lsuhsc.edu](mailto:mcocke@lsuhsc.edu) with your topic and why you think that it is important for the Council to consider it as a policy recommendation.

Other policy recommendations submitted this summer from this council and others can be found at the ASHP House of Delegates website [http://www.ashp.org/s\\_ashp/cat1c.asp?CID=2896&DID=3920](http://www.ashp.org/s_ashp/cat1c.asp?CID=2896&DID=3920).

## Ranexa® (Ranolazine)

Heather Stone, Pharm.D.

### Manufacturer

CV Therapeutics, Inc.

### Therapeutic Class

Antianginal

### How Supplied

500 mg extended-release tablets available in:  
Unit-of-use bottle (60 tablets) or pharmacy bottle (500 tablets)

### Indications and Usage

Ranolazine is indicated for the treatment of chronic angina in combination with amlodipine, beta-blockers, or nitrates in patients who have not achieved an adequate response with other antianginal drugs.

### Warnings

Ranolazine has been shown in clinical studies to prolong the QTc interval in a dose-related manner. Although this effect did not lead to arrhythmias in any patient during clinical studies, other drugs with this potential have been associated with arrhythmias such as torsades de pointes.

### Contraindications

Ranolazine is contraindicated in patients:

- With pre-existing QT prolongation
- On QT prolonging drugs
- With hepatic impairment (Child-Pugh Classes A [mild], B [moderate], C [severe])
- On potent and moderately potent CYP3A inhibitors, such as diltiazem

### Mechanism of Action

The mechanism of action of ranolazine has not been fully elucidated. There are two proposed pathways independent of meaningful changes in hemodynamic parameters such as heart rate and blood pressure.

1. Partial fatty acid oxidation (pFOX) inhibition: Shifts cardiac oxygen production during ischemic conditions from fatty acid oxidation to glucose oxidation, a more oxygen-efficient production of ATP. Also, these effects are thought to reduce increases in lactic acid and cellular acidosis which results from cardiac ischemia.
2. Selective inhibition of the late sodium current ( $I_{Na}$ ): By selectively inhibiting  $I_{Na}$ , calcium overload during ischemia would be decreased and thereby improve myocardial function and myocardial perfusion.

### Pharmacokinetics

- Bioavailability: 76%
- Protein binding: 62% bound to plasma proteins
- Time to peak: 2-5 hours
- Terminal half-life: 7 hours
- Major substrate of CYP3A4 and a minor substrate of

CYP2D6. Weak inhibitor of CYP3A4 and 2D6

### Absorption, Metabolism, and Excretion

Absorption: Highly variable; substrate of P-glycoprotein (Pgp); concurrent use of P-gp inhibitors may increase absorption

Metabolism: Metabolized extensively in the intestines and liver; less than 5% excreted unchanged Metabolized mainly by CYP3A, to a lesser extent CYP2D6

Excretion: Approximately 75% excreted in the urine

### Administration and Dosage

- 500 mg b.i.d. increased, if needed, to a maximum 1,000 mg b.i.d.
- May be taken with or without food; should be swallowed whole and not crushed, broken, or chewed
- Renal impairment: dosage has not been established. Plasma ranolazine levels increased approximately 50% in patients with varying degrees of renal dysfunction. Patients with severe renal dysfunction had an increase in mean diastolic blood pressure of 10-15 mmHg. Monitor blood pressure.
- Dosing adjustments are generally not required for age, gender, or in patients with CHF or diabetes mellitus
- Electrocardiograms (ECGs) should be done at baseline and follow-up
- Dosages of P-gp substrates may need to be reduced
- Dosages of drugs metabolized mainly by CYP2D6 may have to be reduced

### Special Populations

- Pregnancy: Category C
- Nursing Mothers: It is not known if ranolazine is excreted in breast milk
- Pediatrics: Safety and effectiveness in pediatric patients have not been established
- Geriatrics: No overall differences in efficacy. In controlled studies, patients  $\geq 75$  years of age had a higher incidence of adverse events and drug discontinuations due to adverse events.

### Common Adverse Events

Palpitations, vertigo, abdominal pain, dry mouth, nausea/vomiting, dyspnea, and syncope. Flattened and notched T waves.

### Drug Interactions

- Ketoconazole, diltiazem, verapamil and other potent or moderately potent CYP3A inhibitors should not be co-administered.

*Monograph continued on page 6.*

Monograph continued from page 5.

- Co-administration with simvastatin results in about a 2-fold increase in plasma concentrations of simvastatin, and its active metabolites.
- Caution should be exercised when administering with P-gp inhibitors such as ritonavir and cyclosporine.
- Ranolazine has been found to partially inhibit CYP2D6. Concomitant use with other drugs metabolized by CYP2D6, such as tricyclic antidepressants and antipsychotics, may require lower doses of the other drug.
- As a result of P-gp inhibition by ranolazine, digoxin concentrations may increase necessitating a dose adjustment for digoxin.
- Moderately potent CYP3A inhibitors should not be co-administered.
- Co-administration with simvastatin results in about a 2-fold increase in plasma concentrations of simvastatin, and its active metabolites.
- Caution should be exercised when administering with P-gp inhibitors such as ritonavir and cyclosporine.
- Ranolazine has been found to partially inhibit CYP2D6. Concomitant use with other drugs metabolized by CYP2D6, such as tricyclic antidepressants and antipsychotics, may require lower doses of the other drug.
- As a result of P-gp inhibition by ranolazine, digoxin concentrations may increase necessitating a dose adjustment for digoxin.

### Clinical Trials

1. Combination Assessment of Ranolazine In Stable Angina (CARISA): Phase III, multi-national, double-blind, 3-group parallel, placebo-controlled trial to determine if ranolazine improves exercise duration of patients who despite taking atenolol, amlodipine, or diltiazem still exhibit angina and ischemia.

#### Methodology

- 823 patients stratified based on antianginal therapy at time of enrollment
  - 50 mg atenolol [354 (43%)], 5 mg amlodipine [256 (31.1%)], 180 mg diltiazem [213 (25.9%)]
- Randomly assigned to one of three groups

-Ranolazine SR 750 mg (n = 279), 1000 mg (n = 275), or placebo (n = 269) b.i.d. for 12 weeks

#### Results:

Exercise duration (difference from placebo): Background interaction (p = 0.63)

- Primary efficacy endpoint
  - 750 mg: 23.7 sec (p = 0.03)
  - 1000mg: 24 sec (p = 0.03)

#### Conclusions

Ranolazine increased exercise duration and the times to angina and electrocardiographic ischemia in patients with severe chronic angina. The increases were not dependent on changes in blood pressure, heart rate, or background antianginal therapy. Ranolazine also reduced frequency of angina attacks and nitroglycerin use.

2. Efficacy of Ranolazine in Chronic Angina (ERICA): Phase III, multinational, double-blind, placebo-controlled trial to determine if ranolazine reduces angina in patients with persistent angina despite treatment with maximum recommended daily dosage of amlodipine (10 mg/day) over a 6-week period.

#### Methodology

- 565 randomized patients began a 6 week treatment phase
  - 281 received 1,000 mg ranolazine b.i.d.
  - 284 received 10 mg/day of amlodipine given at the same time

#### Results

- Weekly rate of angina attacks: Primary efficacy endpoint
  - Baseline median angina weekly rate = 4.5 per week
  - Ranolazine: 2.88 ± 0.19
  - Placebo: 3.31 ± 0.22
  - p = 0.028

#### Conclusions

The addition of ranolazine 1,000 mg twice a day significantly reduces the frequency of angina episodes and rate of nitroglycerin consumption.

*Final Conclusion and References on page 7.*

### Approximate Cost Comparison

Drug Products	Usual Dose in Angina	Cost (per 30 days)
Ranexa® (ranolazine)	500-1,000 mg po b.i.d.	\$200 to \$400
Tenormin® (atenolol)	50-100 mg/day, may increase to 200 mg/day	\$5 to \$10
Lopressor® (metoprolol)	50-400 mg/day	\$6 to \$28
Norvasc® (amlodipine)	5-10 mg/day	\$45 to \$60
Imdur® (isosorbide mononitrate)	30-60 mg every morning; max 240 mg daily	\$16 to \$60

from Monograph on previous page

#### Final Conclusion

Clinical studies support ranolazine's safety and efficacy for a controlled population. Currently, there are no studies that definitively evaluate outcomes such as reduction in the risk of myocardial infarction or death. Due to ranolazine's propensity for prolonging the QTc interval which necessitates monitoring throughout treatment, therapy with this agent will require a compliant patient, as well as, prescriber. In addition, because of the significant drug interactions and contraindications, benefits of the treatment for chronic angina with ranolazine would only outweigh the risks in patients whose symptoms are not controlled with maximized standard therapies.

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Rousseau RF, Pouleur H, Cocco G, Wolff AA. Comparative efficacy of ranolazine versus atenolol for chronic angina pectoris. Am J Cardiol 2005; 95: 311-316.

Ranexa package insert. CV Therapeutics, 2006.

Mark your calendars and begin  
planning your activities for

**National  
Pharmacy Week  
October 21-27, 2007!**

## **Job Opportunity!**

### **St. Elizabeth Hospital currently has an opening for a Staff Pharmacist.**

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## The LSHP 2007 Midyear Meeting

To book your hotel room, call Sam's Town at 877-429-0711. Rooms are \$125 on Friday night in the LSHP block. Mention the code: S10LSP when reserving.

Brochures are coming soon!



**October 6, 2007  
Sam's Town Hotel & Casino  
Shreveport, LA**

**Don't miss this opportunity for quality continuing education,  
an exhibition, lunch and networking!**

*from Collaborative Practice from page 3*

1. Christensen DB. **Collaborative Drug Therapy Management** agreements—further evidence of acceptance and success. *J Am Pharm Assoc.* 2001; 41:15–6.

2. The Pharmacy Profession: Transitioning from Prescription Provider to Health Care Manager. American Pharmaceutical Association.

3. Louisiana Board of Pharmacy: Laws and Regulation [www.labp.com](http://www.labp.com)