

# The Louisiana Health-System Pharmacist

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More details regarding the upcoming meetings will be released online at <u>https://lshp.org</u> Please submit inquiries and comments regarding LSHP events to <u>office@lshp.org</u>. Thank you!



Hello all,

After a short hiatus, the LSHP newsletter is back! This is a brief version of the newsletter to get us back on track. We hope that you find the information and articles included below helpful. As we get things restarted, the newsletter will return to being published electronically each quarter, approximately 1 month after the LSHP Board Meetings to ensure that the membership is updated on the latest happenings. We also will continue to bring you informative articles and updates from students, residents, and LSHP members across the state. Please see below for the submissions process and guidelines – feel free to share with your colleagues!

This is YOUR newsletter as the membership of LSHP, so if there are specific things you'd like to see included in the future, please let us know at <u>lshpnewsletter@outlook.com</u> or by contacting the office (<u>office@lshp.org</u>).

Jennifer G Smith, PharmD, BCPS Interim LSHP Newsletter Editor

## Words from the Wise

"The greatest of all mistakes is to do nothing because you think you can only do a little."

## Hilary Hinton "Zig" Ziglar (1926-2012)

Author, salesman, motivational speaker

## **Useful Resources**

- Comprehensive, updated medication shortage information from ASHP <u>https://www.ashp.org/Drug-Shortages</u>
- ASHP Covid-19 resource center (includes a regularly updated evidence summary table for available treatments, testing and vaccine information, and tools for hospitals) <u>https://www.ashp.org/COVID-19</u>
- Louisiana Department of Health Coronavirus resource center (includes vaccine information/eligibility and links to many other state-specific resources): <u>https://ldh.la.gov/coronavirus/</u>
- Infectious disease information, links to resources, and articles with a little dose of fun <u>http://www.idstewardship.com</u>



## <u>Camzyos® (Mavacamten): First-In-Class Treatment for Symptomatic Hypertrophic Obstructive</u> <u>Cardiomyopathy</u>

Kayla Thibodaux, PharmD, MBA PGY1 Pharmacy Resident, Slidell Memorial Hospital

Hypertrophic Cardiomyopathy (HCM) is a common and complex heart disease, with an estimated prevalence of 1 in 500 individuals in the United States.<sup>1</sup> HCM is often hereditary and is commonly associated with genetic mutations in cardiac myosin, the motor protein responsible for the contraction of the heart.<sup>2</sup> These mutations lead to over-contraction, causing the heart muscle to become abnormally thick and stiff, prohibiting the heart from relaxing and pumping blood efficiently.<sup>2,3</sup>

When the heart muscle becomes rigid at the septum, barriers are created between chambers that restrict proper blood flow. This type of cardiomyopathy is classified as hypertrophic obstructive cardiomyopathy (HOCM).<sup>4,5</sup> HOCM affects individuals of any race or gender and may present as symptomatic or asymptomatic. Patients with symptomatic HOCM may experience chest pain, difficulty breathing, fatigue, arrhythmias, lightheadedness, syncope, and/or peripheral edema. Disease-related complications include heart failure, atrial fibrillation, thrombosis, and stroke. Current management of HOCM consists of lifestyle modifications and medications for symptom management including beta-blockers, calcium channel blockers, anti-arrhythmics, and diuretics.<sup>5</sup>

In 2022, Camzyos<sup>®</sup> (mavacamten) was approved by the FDA for symptomatic management in adults with New York Heart Association (NYHA) class II–III symptomatic HOCM. Camzyos<sup>®</sup> is a first-in-class cardiac myosin inhibitor that targets the underlying source of HOCM.<sup>6</sup> By inhibiting myosin, Camzyos<sup>®</sup> can decrease obstruction caused by over-contraction to improve functional capacity and symptoms.<sup>7</sup>

Approval was based on outcomes of the EXPLORER-HCM trial, a phase III, multicenter, randomized, doubleblind, placebo-controlled trial that evaluated safety and efficacy in 429 enrolled patients. Patients were included in this study if they were at least 18 years of age with a diagnosis of HOCM, Left Ventricular Ejection Fraction (LVEF) of at least 55%, and NYHA Class II-III symptoms. Compared to placebo, patients receiving Camzyos<sup>®</sup> had greater improvement in post-exercise Valsalva Left Ventricular Outflow Tract (LVOT) gradient, peak oxygen consumption (pVO2), and symptom scores. An additional 34% of patients improved by at least one NYHA functional class in the Camzyos<sup>®</sup> group compared to placebo.<sup>8</sup>

The most common adverse events for Camzyos<sup>®</sup> include dizziness and syncope.<sup>8,9</sup> The U.S. Prescribing Information for Camzyos<sup>®</sup> includes a Boxed Warning for the risk of developing heart failure due to systolic dysfunction. Because of this risk, the Camzyos<sup>®</sup> REMS (Risk Evaluation and Mitigation Strategy) program is required by the FDA to ensure the safe prescribing and usage of this medication. Due to an increased risk of heart failure, concomitant use of Camzyos<sup>®</sup> with moderate to strong CYP2C19 inhibitors, strong CYP3A4 inhibitors, moderate to strong CYP2C19 inducers, or moderate to strong CYP3A4 inducers is contraindicated. Camzyos<sup>®</sup> is not recommended for patients who are pregnant or are planning to become pregnant while receiving treatment.<sup>6,9</sup>

Echocardiogram imaging is required prior to and during treatment with Camzyos<sup>®</sup> to determine eligibility and appropriate dosage. Camzyos<sup>®</sup> is approved for patients with a Left Ventricular Ejection Fraction (LVEF) of 55% or higher. Camzyos<sup>®</sup> is available in 2.5, 5, 10, and 15 mg capsules. The standard starting dose of Camzyos<sup>®</sup> is 5 mg daily, however dosing and adjustments are ultimately determined by LVOT gradients measured on echocardiogram.<sup>6,9</sup>

The out-of-pocket costs for a 30-day supply of Camzyos<sup>®</sup> can be over \$7,000, depending on the prescribed dosage. Commercially insured patients can apply for the Camzyos<sup>®</sup> Co-Pay Program which offers patients a



free 30-day trial and can pay as little as \$10 per month following the trial period. Eligible patients may also receive financial support for required echocardiograms.<sup>6,10</sup>

In summary, Camzyos<sup>®</sup> is the first FDA-approved medication designed to target the underlying cause of HOCM. Clinical trials have shown that Camzyos<sup>®</sup> is more effective than placebo at improving functional capacity and symptoms for patients with symptomatic HOCM. Camzyos<sup>®</sup> can increase the risk of developing heart failure, therefore strict monitoring is required by the FDA through the Camzyos<sup>®</sup> REMS program.

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## Quvivig™(Daridorexant) New FDA Approved Drug for Insomnia

Kourtney Landry, PharmD Candidate; Christopher Gillard, PharmD, BCPS Xavier University of Louisiana College of Pharmacy

Insomnia affects approximately 3 million individuals each year. It is a sleep disorder which prevents patients from going to sleep, staying asleep, waking up early, and contributes to lethargy. Insomnia occurs when there is competition between psychological cognitive arousals, altered circadian mechanisms, and homeostatic mechanisms. This ultimately leads to the inhibition of the sleep-wake switch.<sup>1</sup> Between 31 and 75% of those affected by insomnia classify their cases as chronic. This condition can affect not only patient's quality of sleep, but also disrupts other aspects of life, namely, one's ability to work, concentrate, and contributes to the proliferation of additional comorbid conditions. Risk factors include sex, age, mental/physical health, stress levels, and irregular sleep schedule. Conditions linked to insomnia are broad; chronic pain, cancer, diabetes, heart disease, GERD, Parkinson's Disease and Alzheimer's Disease are just a few. The annual cost of insomnia management is over \$100 billion.<sup>2</sup>

On January 10, 2022, the FDA approved Quviviq<sup>™</sup> for use in adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. It is a schedule IV hypnotic, orexin receptor antagonist that works by blocking the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R, which is thought to suppress wake drive.<sup>3</sup> In patients with insomnia, orexin increases wakefulness while decreasing non-REM and REM sleep.<sup>4</sup>

The studies which led to the approval of Quviviq<sup>TM</sup> were two multicenter, randomized, double-blind, placebocontrolled, parallel-group studies. In both studies, they tested a placebo in comparison to Quviviq<sup>TM</sup> at 25 mg and 50 mg with each group having 310 participants. Inclusion criteria for this study is as follows: patients 18 years or older, patients with insomnia disorder according to DSM-5 criteria, an Insomnia Severity Index score of 15 or greater, and insufficient sleep quantity as collected in a sleep diary.<sup>5</sup> The primary endpoints were Latency to Persistent Sleep (LPS) and Wake After Sleep Onset (WASO) measured in a sleep laboratory at month one then again at month three. At month one, there was a significant reduction in WASO in patients who received the drug versus placebo (p<0.0001) at both the 25 mg and 50 mg dose. The LSP also had a significant reduction for the 50 mg tablet compared to placebo (p<0.0001) as well as the 25 mg tablet compared to placebo (p<0.0005). These effects on insomnia reduction were sustained at three months.<sup>5</sup>

Drug Name	Mechanism of Action	Insomnia Indication	
Quviviq <sup>™</sup> (Daridorexant)	Inhibits the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R.	Insomnia characterized by difficulties with sleep onset and/or sleep maintenance. <sup>3</sup>	
Dayvigo <sup>®</sup> (Lemborexant)	Inhibits the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R.	Insomnia characterized by difficulties with sleep onset and/or sleep maintenance. <sup>6</sup>	
Belsomra <sup>®</sup> (Suvorexant)	Inhibits the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R.	Insomnia characterized by difficulties with sleep onset and/or sleep maintenance. <sup>7</sup>	
Ambien <sup>®</sup> (Zolpidem)	Enhances GABAergic inhibition of neurotransmission in the CNS.	Insomnia characterized by difficulties with sleep initiation. <sup>8</sup>	



Sonata <sup>®</sup> (Zaleplon)	Increases GABA- mediated CI influx into the cell which inhibited neurotransmission.	Insomnia characterized by difficulties with sleep initiation. <sup>9</sup>
Lunesta <sup>®</sup> (Eszopiclone)	Unknown, thought to result from its interaction with GABA receptor complexes at binding domains.	Insomnia characterized by difficulties with sleep onset and/or sleep maintenance. <sup>10</sup>
Restoril™ (Temazepam)	Increases the affinity of the neurotransmitter gamma- aminobutyric acid (GABA) for GABA receptors by binding to benzodiazepine receptors.	Short-term treatment of insomnia (generally 7 to 10 days). For patients having difficulty falling asleep or staying asleep. <sup>11</sup>
Halcion <sup>®</sup> (Triazolam)	Binds to the benzodiazepine site of the gamma-aminobutyric acid-A (GABAA) receptors in the brain and enhances GABA-mediated synaptic inhibition.	Insomnia characterized by trouble in maintaining sleep <sup>12</sup>

Quviviq<sup>™</sup> comes in the form of 25 mg and 50 mg tablets. The recommended dosage to treat insomnia is 25 mg to 50 mg orally 30 minutes before going to bed. The maximum dose is 50 mg/day. For patients who have hepatic impairment, specifically Child-Pugh class B, the maximum daily dosage should be 25 mg. If the patient is Child-Pugh class C, usage of Quviviq<sup>™</sup> is not recommend. There is no dose adjustment for renal impairment. It is also not recommended in elderly patients due to Beers Criteria and increased risk of falls.<sup>3</sup> It is intended for short term use of less than 4-8 weeks. The major side effects (incidence 5% or more in patients) that may be seen in Quviviq<sup>™</sup> include: headache, somnolence, and fatigue. This drug may cause CNS depression and a decreased morning alertness especially when used with other drugs that cause CNS depression. It can also worsen suicidal ideation and behavior, sleep paralysis, and complex sleep behavior (sleep walking). Avoid use with strong CYP 3A4 inhibitors, it will lead to increased absorption of Quviviq<sup>™</sup> which heightens the risk of side effects. Quviviq<sup>™</sup> is contraindicated in patients with narcolepsy.<sup>4</sup>

In summary, Quviviq<sup>™</sup> is a newer oral agent that is available for patients with insomnia who have difficulty falling asleep and/or staying asleep. The current market price for Quviviq<sup>™</sup> is approximately \$491 for a month supply. This medication will give patients an additional Dual Orexin Receptor Antagonist (DORA) option to treat their insomnia in conjunction with their non-pharmacological therapy. DORAs are seen as the 1<sup>st</sup> line for sleep maintenance due to their long half-life.<sup>13</sup> Compared to other drugs used to treat insomnia, Quviviq<sup>™</sup> provides patients with the ability to sleep, while not carrying the risk of respiratory depression that is commonly seen in other drugs used in treating insomnia.<sup>13</sup>

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#### Daprodustat (Duvrog®): An Oral Agent for the Treatment of Anemia in Non-Dialysis Patients

Cloud Ian Cunanan, PharmD Candidate 2023; Tibb F Jacobs, PharmD, BCPS ULM College of Pharmacy

Chronic kidney disease (CKD) is a condition that is characterized by the kidneys' inability to maintain its functions. This disease affects approximately 37 million adults in the United States, and patients can acquire complications that are often encountered as the disease progresses to its later stages.<sup>1</sup> One of the complications associated with worsening CKD is anemia. This secondary condition can lead to cognitive impairment, sleep disturbances, CKD progression, cardiovascular comorbidities, higher mortality, higher healthcare costs, and reduced quality of life.<sup>1,2</sup>

The cause of anemia in CKD is mainly attributed to a decreased production of erythropoietin, a molecule that signals the body to make more red blood cells.<sup>2</sup> Erythropoietin is primarily produced by the kidneys, and its production is stimulated when tissue oxygen levels are insufficient. The body uses the hypoxia-inducible factors (HIF) system to sense inadequate oxygen levels and to produce proteins such as HIF- $\alpha$  and HIF- $\beta$  during hypoxic conditions. These proteins bind to oxygen-sensitive genes in cellular nuclei to increase erythropoietin production and activate genes related to iron metabolism. Then, they are degraded by HIF-prolyl hydroxylases once sufficient oxygen levels are reached. As a patient's kidney function declines, the deficiency in one's erythropoietin concentration becomes more pronounced, and it can be observed by a subsequent reduction in hemoglobin levels. Additionally, it is important to note that adequate iron levels are needed for effective erythropoies to take place.<sup>3</sup> Hence, the current treatment of choice for treating anemia when hemoglobin (Hb) levels are < 10 g/dL in CKD patients not undergoing dialysis are erythropoiesis-stimulating agents (ESA) if transferrin saturation (TSAT) levels are >20% or ferritin levels are > 100 ng/mL.<sup>4</sup>

Daprodustat is a hypoxia-induced factor prolyl hydroxylase inhibitor that acts on the HIF system to inhibit the breakdown of the HIF proteins. This drug's mechanism of action would lead to a continued stimulation of erythropoietin production, increased iron metabolism, and an increase in the number of red blood cells. Daprodustat is a novel agent produced by GlaxoSmithKline as the brand Duvroq®.<sup>5</sup> This drug is currently approved in Japan, and its use in both dialysis and non-dialysis patients is still being studied in the United States as it awaits FDA approval. Furthermore, it is unknown how daprodustat compares with ESAs in the treatment of anemia of CKD. A study published on December 6, 2021, aimed to evaluate and compare the safety and efficacy between daprodustat and darbepoetin alfa (an ESA) in treating anemia of CKD in non-dialysis patients.

This Phase 3, multinational, randomized, open-label trial was named the ASCEND-ND trial, and it consisted of 3,872 patients that were randomly assigned to receive daprodustat or darbepoetin alfa. The patients were followed every 4 weeks during the first year of the study and at least every 12 weeks thereafter to achieve and maintain a Hb goal level between 10.0 to 11.0 g/dL. To be included in this study, participants must be Stage 3 to 5 CKD patients, not receiving dialysis or scheduled to start within 90 days, serum ferritin >100 ng/mL and transferrin saturation above 20%, hemoglobin level of 8.0-10.0 if not already receiving ESA, and Hb level of 8.0-11.0 if already receiving ESA. Patients were excluded if they had anemia unrelated to CKD, a recent cardiovascular event, or recent cancer. The primary outcomes of this study aimed to establish noninferiority. Daprodustat's efficacy would be declared noninferior to darbepoetin alfa if the difference in the mean change in Hb baselines between the treatment arms is > -0.75 g/dL, and its safety would be declared noninferior if the hazard ratio was < 1.25 when comparing the first occurrences of a major adverse cardiovascular event (MACE). The secondary outcomes tested for superiority and examined the time to the first occurrence of a MACE, first occurrence of a thromboembolic event, first occurrence of hospitalization for heart failure, and first occurrence of CKD progression.

In this study, the primary outcomes that analyzed the safety and efficacy of daprodustat met the criteria for noninferiority when it was compared to darbepoetin alfa. There was a 0.08 g/dL difference in Hb level change



(95% CI, 0.03 to 0.13, p < 0.001) which meant that the noninferiority criteria for efficacy was met. A hazard ratio of 1.03 (95% CI, 0.89 to 1.19 p < 0.005) was achieved when comparing the occurrence of a first MACE, and a hazard ratio of 1.40 (95% CI, 1.17 to 1.68) was achieved when comparing the occurrence of a first MACE 28 days after the last dose. This indicates that noninferiority for safety was met for the first measurement, but it was not met on the second comparison. Additionally, the results for the secondary outcomes were not statistically significant because the confidence intervals for each result failed to meet the criteria that defines superiority.

	Daprodustat <sup>6</sup>	Darbepoetin alfa <sup>6</sup>	
Primary	<ul> <li>Efficacy:</li> <li>Mean Hb level change from baseline in weeks 28-52 was 0.74±0.02 g/dL</li> <li>Safety:</li> <li>First MACE occurred in 378 of 1937 patients (19.5%)</li> <li>First MACE 28 days after the last dose occurred in 14.1% of patients</li> </ul>	<ul> <li>Efficacy:</li> <li>Mean Hb level change from baseline in weeks 28-52 was 0.66±0.02 g/dL</li> <li>Safety:</li> <li>First MACE occurred in 371 of 1935 patients (19.2%)</li> <li>First MACE 28 days after the last dose occurred in 10.5% of patients</li> </ul>	
Secondary	Results not significant	Results not significant	

The authors of the study concluded that daprodustat appears to be noninferior to darbepoetin alfa in cardiovascular safety and in increasing and maintaining hemoglobin levels in the treatment of anemia of CKD in patients not receiving dialysis. This conclusion seems to accurately reflect the results of the study. However, some of the findings of this study require attention. Higher incidences of cancer-related death, tumor progression, tumor recurrence, and esophageal and gastric erosions in daprodustat were some of the adverse events encountered in this study. This data also showed that daprodustat is unlikely to slow the progression of CKD, so its integration into current practices and guidelines may be a challenge.

Although the ASCEND-ND trial has not solidified the future of daprodustat in non-dialysis patients, another trial has seen greater support for daprodustat in a different population. The ASCEND-D trial evaluated the safety and efficacy of daprodustat in treating anemia of CKD in dialysis patients. The results of this study also showed that daprodustat was noninferior to an ESA control in improving or maintaining Hb levels within target levels, and it was also noninferior in the occurrence of MACE. Recently, a committee that provides the FDA with expert advice regarding new medicines, the Cardiovascular and Renal Drugs Advisory Committee (CRDAC), supported that the benefit of treatment with daprodustat outweigh the risks for CKD patients who are on dialysis with a 13 to 3 vote. The CRDAC, on the other hand, did not support that the benefit of treatment with daprodustat outweigh the risks for 11 vote.<sup>7</sup>

Even with the results of the ASCEND-ND trial, many questions remain unanswered regarding daprodustat's role in the treatment of anemia of CKD in non-dialysis patients. It is still unknown how daprodustat would compare to other ESAs due to differences in pharmacokinetic properties. Additionally, post-marketing findings in Japan could further support or challenge the approval of this medication in the United States. If additional evidence can be provided strengthening the efficacy and safety of daprodustat, it has the potential to be a promising oral treatment alternative for the treatment of anemia of chronic kidney disease.

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#### Upcoming Events

There are many ways to get involved with LSHP, whether it's a one-time volunteer opportunity, attending a meeting, participating in a committee, or becoming a local or state officer. Please join us at any of the upcoming events and/or reach out to your local chapter or the LSHP office for more information on getting involved in areas that interest you!

Date & Time	Event Title & Activity Number	Location & Sponsoring Chapter
3/7/23 6:00 PM	Review of Multiple Sclerosis Medications and Management of Acute Events in the Inpatient Setting Speaker: Kayla Thibodaux, PharmD, MBA UAN# 0179-0000-23-005-L01-P/T	Virtual via Zoom LSHP-Southeast Chapter
3/13/23 11:00 AM	Safety First: preventing medication errors in the hospital setting Speaker: Alexis McDaniel, PharmD UAN# 0179-9999-23-004-L05-P/T	Woman's Hospital Baton Rouge, LA
3/14/23 6:00 PM	Anemia and Iron Deficiency in Heart Failure Speaker: Caiyun Jane Yang, PharmD UAN# 0179-0000-23-007-L01-P/T	Virtual via Zoom LSHP – Southeast Chapter
3/15/23 8:00 AM to 5:30 PM	NADDI- 2023 Drug Diversion Training Conference Multiple speakers Total of 6 credit hours	Lafayette Sheriff's Public Safety Complex 1825 W. Willow St., Scott, LA http://www.naddi.org/trainings
3/30/23 10:30 AM	Treatment of Staphylococcus Aureus Bacteremia Speaker: Parichehr Shoureshi, PharmD UAN# 0179-9999-23-006-L01-P/T	Woman's Hospital Baton Rouge, LA

\*Please contact the LSHP Office (office@lshp.org) for more information on any of these events.



Please submit newsletter-related comments, questions, and potential publishable content to LSHPnewsletter@outlook.com. Thank you!

Please reference the checklist and article submission guidelines to help us standardize the submission process for the newsletter. To avoid duplication of work, please contact us prior to starting work on an article to ensure that there are no other pending articles with duplicate information.

## LSHP Newsletter – Content Submission Checklist

#### Title/Cover Page:

- \_\_\_\_Name of all authors with professional degrees, job title, and contact information (e-mail)
- \_\_\_ For student pharmacists and student technicians, please include year of graduation, school,
- and name of reviewing pharmacist or pharmacy technician.
- \_\_\_ Disclosure of any conflicts of interest
- Title of article clearly reflects / relates to the content within
- \_\_\_ All text uses Times New Roman, size 12 font

## Article Text:

- \_\_\_ All text is Times New Roman, size 12 font
- All abbreviations are clearly defined
- \_\_\_ Descriptive headings are used to identify major sections

## Photos and Figures (if applicable):

- Photos / figures are submitted in high resolution .jpeg or .png format
- \_\_\_ Source of photo / figure is referenced appropriately

## Consent:

- \_\_\_ Consent given for any name(s), other than authors, that is included in the article
- \_\_\_ Consent received from individuals appearing in any photos
- Received written permission to use copyrighted material from publisher/organization or individual who holds copyright

## References:

- \_\_\_ References are placed under a bolded heading "References"
- \_\_\_ References are formatted in American Medical Association style
- \_\_\_ References within text, figures, or tables are noted with superscript Arabic numbers



## LSHP Newsletter – Content Submission and Approval Process (General Outline)

#### I. Student Pharmacists (PharmD candidates)

LSHP welcomes the submission of new-literature review articles, original research, practice or medication updates, and other relevant content from student pharmacists in Louisiana to be featured in our periodical newsletter. A general guideline of the content submission process is outlined below. Questions and content can be directed to <u>LSHPnewsletter@outlook.com</u>

a. Student pharmacists wishing to submit content for consideration for publication in the LSHP newsletter should be currently enrolled in a school of pharmacy located within Louisiana.

b. Student pharmacists must choose at least one advisor/preceptor who is a registered pharmacist in Louisiana to act as *sponsor and co-author* as the student develops their content.

c. The sponsoring pharmacist(s) should be involved with all phases of content development - selecting the subject, reviewing quality of any literature to be discussed, outlining the discussion, ensuring adequacy of references and evidence, and producing preliminary and final drafts.

d. All e-mail communications between the student pharmacist author(s) and the LSHP newsletter staff should copy ("cc") the sponsoring pharmacist(s) to maintain their involvement.

e. When the student pharmacist author(s) and sponsoring pharmacist(s) have selected a subject for potential publication in the LSHP newsletter, they should submit their topic (along with attachment of any relevant literature or source material) to the LSHP newsletter editors/LSHP office for initial review.

f. LSHP newsletter staff will judge the appropriateness of the topic based on its relevance to the LSHP member audience, application to health-system pharmacy, relative impact of findings, and avoidance of duplication of recent newsletter content. LSHP newsletter will then notify the student pharmacist(s) if the submitted topic is approved based on the considerations listed above.

g. As the student pharmacist(s) work with sponsoring pharmacist(s) to develop their content for submission to the LSHP newsletter, they may submit an initial draft to the LSHP office. LSHP newsletter staff will review the draft and note any requests for revisions (for appropriate grammar, length, level of discussion, references, etc.) within a goal timeframe of 2-3 weeks.

h. The student pharmacist(s) should work with their sponsors to make all necessary revisions and refinements, and submit a subsequent draft to the LSHP office within a goal of 2-3 weeks.

i. LSHP newsletter staff will reply with any final requests for adjustments and revisions as well as give notice as to which newsletter edition in which the content may appear. All listed authors of content will also need to sign, complete, and submit a Disclosure Notice before publication.

#### II. Post-Graduate Pharmacists (Residents, Fellows, MBA / MHA / MS / PhD candidates)

LSHP welcomes the submission of new-literature review articles, original research, practice or medication updates, and other relevant content from post-graduate pharmacists in Louisiana to be featured in our periodical newsletter. A general guideline of the content submission process is outlined below. Questions and content can be directed to LSHPnewsletter@outlook.com



a. Post-graduate pharmacists wishing to submit content for consideration for publication in the LSHP newsletter should be currently training in a program located in the state of Louisiana.

b. Post-graduate pharmacists should inform their residency program director / faculty advisor / research sponsor of their decision to submit content for publication in the LSHP newsletter. The post-graduate pharmacist should include any documentation of approval of their intent and topic.

c. For new-literature review articles, practice or medication updates, and other non-original research topics, a sponsoring pharmacist or co-author is not required (only require approval by a program leader to submit content to LSHP newsletter). However, *for submissions of original research* proceeding under the direct supervision of one or more faculty advisors or sponsors, the directly supervising program leader should be involved with all phases of content submission by the post-graduate pharmacist – such as outlining the research project, ensuring adequacy of methods, analyzing and discussing the findings, and producing preliminary and final drafts.

d. When the post-graduate pharmacists have selected a subject with director / advisor / sponsor approval for potential publication in the LSHP newsletter, they should submit their topic (along with attachment of relevant literature or source material) to the LSHP newsletter editors/LSHP office for initial review.

e. LSHP newsletter staff will judge the appropriateness of the topic based on its relevance to the LSHP member audience, application to health-system pharmacy, relative impact of findings, and avoidance of duplication of recent newsletter content. LSHP newsletter will then notify the post-graduate pharmacist if the submitted topic is approved based on the considerations listed above.

f. As the post-graduate pharmacists develop their content for submission to the LSHP newsletter, they may submit an initial draft to the LSHP office. LSHP newsletter staff will review the draft and note any requests for revisions within a goal timeframe of 2-3 weeks.

g. The post-graduate pharmacists should make all necessary revisions and refinements and submit a subsequent draft to the LSHP office within a goal timeline of 2-3 weeks.

h. LSHP newsletter staff will reply with any final requests for adjustments and revisions, as well as give notice as to which newsletter edition in which the content may appear. All listed authors of content will also need to sign, complete, and submit a Disclosure Notice before publication.

## III. Practicing Pharmacists and Pharmacy Technicians ("Practitioners")

LSHP welcomes the submission of new-literature review articles, original research, practice or medication updates, and other relevant content from practicing pharmacists and pharmacy technicians ("practitioners") in Louisiana to be featured in our periodical newsletter. A general guideline of the content submission process is outlined below. Questions and content can be directed to <u>LSHPnewsletter@outlook.com</u>

a. Practitioners wishing to submit content for consideration for publication in the LSHP newsletter should be currently licensed and practicing pharmacy in the state of Louisiana. Consideration can be given for out-of-state practitioners if the content is of particular merit.

b. For new-literature review articles, practice or medication updates, and other non-original research topics, a sponsoring pharmacist or co-author is not required (only require approval by a program leader to submit content to LSHP newsletter). However, for submissions of original research, any co-investigators involved in the research process should be noted as co-authors, and ideally should be involved with the steps of the content submission process.



c. When practitioners have selected a subject for potential publication in the LSHP newsletter, they should submit their topic (along with attachment of relevant literature or source material) to the LSHP office for initial review.

d. LSHP newsletter staff will judge the appropriateness of the topic based on its relevance to the LSHP member audience, application to health-system pharmacy, relative impact of findings, and avoidance of duplication of recent newsletter content. LSHP newsletter will then notify the practitioner if the submitted topic is approved based on the considerations listed above.

e. As the practitioners develop their content for submission to the LSHP newsletter, they may submit an initial draft to the LSHP office. LSHP newsletter staff will review the draft and note any requests for revisions within a goal timeframe of 2-3 weeks.

f. The practitioners should make all necessary revisions and refinements and submit a subsequent draft to the LSHP office within a goal timeline of 2-3 weeks.

g. LSHP newsletter staff will reply with any final requests for adjustments and revisions, as well as give notice as to which newsletter edition in which the content may appear. All listed authors of content will also need to sign, complete, and submit a Disclosure Notice before publication.