

Yital/

Fall 2020, Issue 13

Message from the President

Hello OCCP Members,

I hope you had a productive and restful summer! Our organization has several important updates for the remainder of this year.

In order to protect the health of our members, the executive committee has chosen to cancel the in-person Fall OCCP meeting. The Spring OCCP meeting was also cancelled; however, we will be offering virtual continuing education and a business meeting in place of the Fall 2020 in-person meeting.

Both medication safety and law continuing education will be available to OCCP members at no cost. Options for meeting registration and OCCP membership are also available for current non-members. A live, virtual business meeting will also take place on October 13. Look forward to updates on the Spring meeting in the upcoming months.

Message from the President continued on page 2

OCCP Leadership

Sarah Petite, PharmD, BCPS President Liz Fredrickson, PharmD, BCPS President-Elect Steering Committee Chair Kelsey Rife, PharmD, BCACP **Immediate Past President** Katie Rivard, PharmD, BCPS, BCIDP, AAHIVP **Planning Committee Chair** Jessica Hoover, PharmD, BCPPS Secretary/Treasurer Andrea Pallotta, PharmD, BCPS, BCIDP Membership Committee Co-Chair Eve Hackett-Garr, PharmD, BCPS, BCIDP Membership Committee Co-Chair Karissa Kim, PharmD, BCPS Membership Committee Co-Chair SCCP chapter liaison Ellen Immler, PharmD, BCCCP Nominations Committee Chair Geralyn Waters, PharmD, BCPS Advocacy Committee Co-Chair Katelyn Simmons, PharmD, BCACP Advocacy Committee Co-Chair Julia Kuroski, PharmD, BCCCP **Communications Committee Co-Chair** Keith Posendek, PharmD, BCPS, BCGP Newsletter Editor **Communications Committee Co-Chair**

Fall Meeting

Tuesday, October 13th 2020 from 12-1PM

Virtual Business Meeting Kick-Off Meeting link to be sent to all OCCP members!

- Recorded virtual CE will be available 10/15 to 12/31/2020:
- Ohio Pharmacy Law Update, Donnie Sullivan, RPh, PhD
 - Medication Safety, Dr. Casey Moore, PharmD

Registration

Business meeting and CE is **FREE** for OCCP members!! OCCP non-members: Meeting Registration + 1 year membership Pharmacist: \$50 Pharmacy Resident: \$25 Pharmacy Student: \$5 OCCP non-members: Meeting Registration + 3/mo membership (access to CE content) Pharmacist: \$35 <u>https://www.occpweb.org/membership#join</u>

Message from the President continued

President Message continued from page 1

We hope you find the medication safety and law continuing education beneficial for your practice. The COVID-19 pandemic has changed the way our organization can meet and we look forward to exploring more virtual continuing education options in the future.

We appreciate your feedback and are continuing to work to develop our organization to meet your needs.

Our updated website has additional information on current OCCP news and up to date meeting information. While you are there, please remember to renew your membership dues.

I want to thank the committee chairs and members for their continued hard work.

Our organization could not be successful without the dedication of our committee members. If you are interested in joining a committee, you can volunteer on the Committee Membership page of our website's members only content.

Sarah Petite



Planning Committee Update

The OCCP Fall 2020 Meeting will be held virtually this year! We will start off with a virtual business meeting on Tuesday, October 13th from 12-1PM.

The link for attendance will be sent to all OCCP members. Recorded virtual CE will be available on the OCCP website from 10/15/2020-12/31/2020. One hour of Pharmacy Law and Medication Safety CE will be available and **free** to all OCCP members!

For OCCP non-members, registration + 1 year of membership will be \$50 for pharmacists, \$25 for pharmacy residents, and \$5 for pharmacy students. Pharmacists may also register for a 3month OCCP membership to gain access to the virtual CE content for \$35.

Thank you,

Katie Rivard



Membership Committee Update

We now have the rolling membership and it seems to be going very smoothly and people are all automatically getting alerts as to when their memberships are expiring and asking them to renew. This has been a great new process and saves a lot of time.

We are planning to meet in September, if able, for a teleconference to discuss any new ideas/changes and how to best encourage student involvement with the next academic year since things are all looking slightly different.

The planning committee brought out the idea of tying inmeeting registration for the Fall meeting with OCCP memberships as follows:

- Current OCCP member = free
- Non-OCCP member =
- \Rightarrow \$50 for meeting registration + 1 year OCCP membership
- ⇒ \$35 for meeting registration + 3 month OCCP membership (essentially would give access to members only website for a small amount of time to have access to/complete

CE)

- Pharmacy Residents =
 - \Rightarrow \$25 for meeting registration + 1 year OCCP membership
- Student Pharmacists =
- \Rightarrow \$5 for meeting registration + 1 year OCCP membership

Thank you,

Eve Hackett-Garr: HACKETE@ccf.org

Karissa Kim: kimky@ucmail.uc.edu

Andrea Pallotta: pallota@ccf.org



Advocacy Committee Update

Please save-the-date for the Ohio Pharmacy Advocacy Forum, which will be held virtually on **Friday, September 25, 2020**. The forum focus is *COVID-19 and the Pharmacist*. The global COVID-19 pandemic has served as a catalyst for greater traction on overcoming obstacles to expansion of the pharmacist's ability to deliver patient care.

The role of pharmacists in this national emergency has grown. The forum will include: (1) a keynote presentation by OPA Director of Government & Public Affairs, Antonio Ciaccia, including the executive director of the Ohio Board of Pharmacy, Steve Schierholt, Esq.; (2) a feature presentation by Stuart Beatty, OPA's Director of Strategy and Practice Transformation; (3) a pharmacy directors' panel moderated by Executive Vice President and CEO of APhA, Scott Knoer, MS, PharmD, FASHP; (4) a legislators' panel; and (5) pharmacy advocacy "pearls" session of how Ohio pharmacists provided innovative services during this time of need.

The Forum is presented by our organization, OCCP, in collaboration with the Ohio Northern University Raabe College of Pharmacy, the Ohio Pharmacists Association, and the Ohio Society of Health-System Pharmacists. This event is completely free to attend. Please register and share the following link with your peers, colleagues, and students! http://ohiorxadvocacy.com/

In addition to Ohio's advocacy efforts, national pharmacy organizations, including ACCP, have come together with four recommendations for immediate adoption: (1) authorize test-treatimmunize, (2) ease operational barriers to address workforce and workflow issues, (3) address shortages and continuity of care, and (4) reimburse for services and remove barriers. More information available here.

Stay safe and healthy, and we will continue to provide advocacy updates as they arise!

Thank you,

Geralyn Waters, PharmD, BCPS

Katie McMillan, PharmD, BCACP



Communications Committee Update

As previously mentioned, last Fall we released our updated OCCP website. If you have any questions regarding your account or the website in general, please contact Julia Kuroski (kuroskj@ccf.org) or through the website at <u>https://</u> <u>www.occpweb.org/contact</u>.

Thank you to all the individuals that submitted articles for the Fall newsletter. Thank you to Sandra Axtell, Jessica Traeger, Julia Kuroski and Sarah Petite for reviewing the newsletter article submissions.

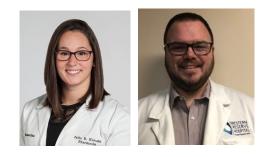
If you are interested in writing an article or helping to review articles for future OCCP newsletters, please contact Keith Posendek (kposendek@westernreservehospital.org), or submit an article via our website (occpweb.org). We are looking for a clinical pearl and a new drug update for the Spring newsletter. Requirements include \approx 500 words maximum, clinically relevant topic, and at least one author is an OCCP member.

The communications committee has resident and preceptor spotlights featuring one resident and one preceptor a quarter on the OCCP Facebook/Instagram page and newsletter. If you would like to nominate a resident or preceptor for this feature, submission information is available on the OCCP Facebook page or website. Be sure to follow us on social media to stay up to date with all OCCP activities!

Facebook: Ohio College of Clinical Pharmacy

Instagram: _OCCP

Julia Kuroski and Keith Posendek



Nominations Committee Update

The Spring awards (BPS and Pharmacist of the Year) were delayed due to COVID-19 pandemic. The new deadline for applications is September 18th. A more detailed description and application information for each award can be found online at https://www.occpweb.org/ in the "Member Only" section.

The Fall award (Student Travel Scholarship) has been modified to cover cost of registration for the ACCP annual meeting that is to be held virtually.

The deadline for application is also September 18th.

Thanks.

Ellen Immler



Residency Advisory Committee Update

The Resident Advisory Committee (RAC) was developed this year \blacklozenge to promote resident leadership within OCCP.

Members of this committee will work together to develop resident and student-focused programming, activities, and resources; assist with recruiting residents and students to join OCCP, and provide input to, and assist, other OCCP committees.

- Shivali Singh, VA Northeast Ohio Healthcare System
- Kathrine Distel, Summa Health—Akron City Hospital

We would like to congratulate the new members of this committee and thank them for their commitment to OCCP!"

The members of the 2020-2021 RAC are:

- Morgan Cutting (Chair), University of Toledo Medical Center
- Anthony Ross, UH Cleveland Medical Center

Student Chapter Update University of Toledo

The spring semester of the 2019-20 academic year posed quite a tally revealed that the P3 class was indeed "smarter than a P1" few challenges for many of us. The University of Toledo College as they placed first, followed by the P1 team in second, and a P2 College of Clinical Pharmacy (SCCP) chapter managed to be very help fund future Medical Mission Trips. A special thank you to active despite nearly half of the semester being unexpectedly our very talented host for the evening, Vincent Mauro, PharmD, converted to an online setting. As always, our chapter members FCCP. made the most of their time together and were able to host many events and fundraisers.

annual Hygiene Kit Drive to benefit the University of Toledo's Medical Mission Trips to Central America. The "Drive" was supplemented with a "Coin Wars" event in which the P1, P2, and P3 classes competed to raise additional money to help fund additional hygiene kits. Unfortunately, due to the COVID-19 pandemic, this medical mission trip was not able to take place this year.

The third annual "Are You Smarter Than a P1?" trivia night was a Mackzum, Megan Shulkosky, Hannah Hixenbaugh (alternate), fun way for students to test their knowledge of the material taught to students within their first year of the PharmD professional program against their peers. Teams from the P1, P2, and P3 classes competed by answering questions from the P1 curriculum with hopes of being crowned champions. The final point

of Pharmacy and Pharmaceutical Sciences (UTCPPS) Student team in third. All proceeds raised in the event were donated to

The UTCPPS SCCP chapter is proud to announce that our ACCP Clinical Research Challenge team placed within the top 20 teams Starting things off in January, the chapter began their fourth in the nation after advancing to the third round of the competition. The team members are pictured below. Standing(L-R): Ryan Strausbaugh (Captain), Austin Verhoff; Sitting (L-R): Elise Illius (alternate), Bianka Ahmetspahic.

> In addition to the chapter seeing success in the ACCP Clinical Research Challenge, a team was selected to compete in the ACCP Clinical Pharmacy Challenge in the upcoming fall semester. Congratulations to Maureen Hickey (Captain), Courtney and Erik Wasowski (alternate).

> > University of Toledo Update continued on page 5

University of Toledo Update continued from page 4

In mid-March, the University of Toledo transitioned classes to an online setting as a result of the COVID-19 pandemic. With many students self-isolating, the executive board did an excellent job keeping the chapter updated through email communication.

As the spring semester came to a close, the 2020-2021 Executive Board was elected in the chapter's first-ever online election. The Executive Board also held its first ever virtual strategic planning meeting this summer.



Pictured below starting at the top left: Alana Knapke (Programming Coordinator). Nicole Wendeln (Treasurer), Ryan Strausbaugh (President), Hailee Sens (Historian), and Holden Pelz (President-Elect). Not pictured: Katherine Matousek (Secretary). The newly elected Executive Board is excited to take-on a primarily online Fall 2020 semester with plans to keep the organization active in virtual settings.

Approaching the fall 2020 semester the chapter is excited to take on the challenges associated with distance learning and has safety as a top priority. With this in mind, many virtual op-

tions are expected to be explored, such as hosting the 7th annual Trivia Night virtually on Zoom, with all proceeds being donated to the Community Care Clinic, a multidisciplinary, student-driven, free health clinic that serves unin-



sured and underinsured citizens in Northwest Ohio. Despite being unable to host any physical gatherings, the UTCPPS SCCP chapter has plans in place to remain a very active chapter with a strong focus on helping to advance the professional development of our members while benefiting our community!

Student Chapter Update Cedarville University

Our SCCP executive committee at Cedarville University of School of Pharmacy has worked diligently over the past several months to prepare for a number of exciting, upcoming events.



To bring clinical pharmacy to the forefront in a way that will be most impactful for students, we have purposed to collaboratively incorporate our Pediatrics PRN and CNS PRN groups as focal points for several of our

chapter meetings and events. For instance, our CNS PRN will be

working with our school's SNPhA chapter to present a meeting emphasizing mental and behavioral health.

Moreover, we will be partnering with our Phi Lambda Sigma chapter to create a virtual APPE rotations preparation session alongside our region's APPE preceptors. This will provide additional context to upcoming fourth-year pharmacy students as they transition into these rotations.

Although our current pandemic has posed a number of challenges to hosting some of these meetings and events, it has also

Cedarville University Update continued on page 6

Cedarville University Update continued from page 5

presented a number of opportunities to accommodate more students and pharmacists outside of our region.

Overall, our SCCP executive committee remains dedicated to fostering the professional growth of our students in areas of clinical pharmacy, and we eagerly anticipate working alongside our faculty and students to accomplish this.



Student Chapter Update University of Cincinnati

The University of Cincinnati College of Pharmacy ACCP student chapter held an executive board meeting in July to discuss event ideas for the upcoming year amidst the switch to virtual learning at our college. One of the changes we initiated, was making a Microsoft Teams group for our members and other students to participate in our events.

This spring members honored our active-duty troops and veterans by designing and drawing thank-you cards to be sent to troops here in the states and overseas. The UC ACCP chapter also hosted the Local ACCP Clinical Pharmacy Challenge virtually through Microsoft Teams. Despite the challenges, our winning team is going to compete nationally during the virtual national ACCP meeting.



The UC ACCP chapter also held their first general body meeting the on August 31st. The meeting hosted Dr. Eric Mueller and Dr. Christopher Droege from UCMC, who are established members of ACCP,



Our chapter recognized the disconnection virtual learning can create, therefore, our executive board decided to e-mail students weekly to update them regarding events taking place locally, regionally, and nationally. A calendar has also been updated with links to all of our future teams meetings.

with Dr. Mueller being a Fellow of ACCP. They introduced ACCP to our upcoming class of 2024 and provided advices regarding virtual learning.

Student Chapter Update University of Findlay

As many have encountered, spring semester led to many challenges and changes for us. In the beginning of spring semester, Lorin Wise, Mercedes Snyder and Celina Lugo participated in the Clinical Research Challenge. Just prior to the pandemic, the University of Findlay Student College of Clinical Pharmacy was planning to participate in point of care testing within the university and surrounding community. Although this was postponed, multiple organizations within the College of Pharmacy, including SCCP, SSHP and Rho Chi, came together to present a Residency Showcase via Zoom. Two University of Findlay Alumni, Eric Manning, PharmD and Joe Guidos, PharmD, BCPS, BCCP, presented

for students to learn more about what it means to be a resident and the type of experience that is encountered.

At the end of the semester the organization welcomed a new Executive Board: Mercedes Snyder (President), Nerissa Wan (President-Elect), Tecca Ringler (Secretary), Addy Sember (Treasurer), Celina Lugo (Community Service Chair), Lana Elia (Student Liaison), Kathrine Arnes (Fundraising Chair) and Ali Burdick (Professional Development Chair).

Now that we are back on campus this fall, we have many exciting events and fundraisers that we plan to host. First, Megan Lofaso, Allison Burdick, Tecca Ringler and alternates, Mercedes Snyder and Katherine Arnes are preparing for the Clinical Phar-

macy Challenge in the beginning of September. In October, we

care testing events that we plan to hold once we are able to go out into the community. Although there are many changes that still present themselves everyday, we are optimistic that the University of Findlay Student College of Clinical Pharmacy will have a very successful school year.

Student Chapter Update The Ohio State University

We are a newly formed chapter at Ohio State!

We are looking forward to serving our community and showing the impact that a clinical pharmacist can have on the healthcare system. We also hope to expose our membership to the mission and vision of ACCP, driving positive change in optimization of pharmacotherapy and prevention and treatment of disease!

We will be participating as an organization in the Clinical Pharmacy Challenge and will be having pharmacists from different practice sites share their experiences in their practice settings during our general body meetings this semester.

We would love to have OCCP members come and share their experiences in clinical pharmacy, research, and/or other unique roles!



Clinical Pearl

A Case of Cannabinoid Hyperemesis Syndrome in the Hospital Setting

Austin M. Newell, PharmD Candidate; Gwendolyn M. Knowles, PharmD Candidate,

Julie A. Murphy, PharmD, FASHP, FCCP, BCPS;

University of Toledo College of Pharmacy and Pharmaceutical Sciences

presentation. Patient reported missing last insulin dose; blood glucose was 410 mg/dL. Blood glucose control improved over the next three days, but nausea, vomiting and abdominal pain persisted. Patient received three doses per day of ondansetron 4mg 12.5mg intravenously, and four doses per day of metoclopramide 10mg intravenously. Most episodes of emesis occurred in the morning and the patient was taking hot showers frequently throughout the day to relieve symptoms. The diagnosis of cannabinoid hyperemesis syndrome was proposed based on symptomatology and the patient's reported history of illness associated with marijuana use.

Cannabinoid hyperemesis syndrome (CHS) is a subcategory of cyclic vomiting syndrome. The proposed mechanism is the chronic overstimulation of the body's endogenous cannabinoid receptors secondary to chronic cannabis use. This results in the to abstain from marijuana use. downregulation of anti-emetic cannabinoid receptors in the brain, inducing a hyper-emetic state.¹ This mechanism may seem counterintuitive, as marijuana has shown benefit in patients with malignancy due to its antiemetic properties.² Another theory is that prolonged abuse leads to accumulation of cannabis and its metabolites in the adipose tissue. This leads to a steady re- 2. lease of these substances over time, causing decreased gastrointestinal motility and promoting pro-emetic effects.²

CHS is associated with intractable emesis, that is non-responsive to antiemetics, dehydration, and abdominal pain that can last for several days. CHS follows a three-phase cycle which includes 1) prodromal symptoms consisting of early morning nausea, anorexia, and abdominal discomfort, 2) hyperemesis, and 3) recovery until symptoms reappear the next day. The hyper-emetic state can vary in duration from patient to patient.² Patients with CHS are also known to take frequent hot showers to relieve their symptoms.¹

Abstinence from cannabis is the only effective method to prevent recurrent CHS. Based on case reports/series, benzodiazepines, haloperidol, or topical capsaicin seem to have some benefit with lorazepam resolving symptoms acutely.² In one case, a 30-year-old man presented after three days of abdominal pain, nausea, and intractable vomiting only relieved by hot showers. He reported smoking cannabis daily for years, last smoking three days before admission. The abdominal pain and nausea were not relieved by multiple analgesics or antiemetics. The patient then

A 20-year-old female reported to the emergency department received lorazepam 1mg every four hours as needed with procomplaining of abdominal pain, nausea, and vomiting. Past med- methazine 12.5mg as needed. This regimen led to the resolution ical history includes uncontrolled type 2 diabetes mellitus and of his symptoms after four days.³ Another case of CHS occurred chronic daily marijuana usage, with last use 3 hours before in a 28-year-old man with a history of daily marijuana use for ten years. He presented with gastric pain, nausea, and vomiting that persisted for two weeks. The patient stated that smoking more marijuana worsened his condition, but he did find relief by soaking in a hot bath for hours each day. After receiving a lorazepam intravenously, one to two doses per day of diphenhydramine 1mg injection, his condition improved within minutes and resolved within twelve hours.⁴

> After a literature search, it was decided to administer lorazepam 1mg intravenously twice daily for two days and observe the progression of the patient's symptoms, which successfully resolved within this time frame. The frequency of lorazepam administration was based on specific patient factors as well as discussion with the medical team to determine the safest regimen. The patient was counseled to abstain from marijuana. Following discharge, the patient has since returned to the emergency department multiple times for similar signs and symptoms while failing

References:

- Richards JR, Lapoint JM, Burillo-Putze G. Cannabinoid hyperemesis syn-1. drome: potential mechanisms for the benefit of capsaicin and hot water hydrotherapy in treatment. Clin Toxicol (Phila). 2018;56(1):15-24. doi:10.1080/15563650.2017.1349910
- Richards JR. Cannabinoid Hyperemesis Syndrome: Pathophysiology and Treatment in the Emergency Department. J Emerg Med. 2018;54(3):354-63.
- Price SL, Fisher C, Kumar R, Hilgerson A. Cannabinoid hyperemesis syndrome as the underlying cause of intractable nausea and vomiting. J Am Osteopath Assoc. 2011;111(3):166-9.
- 4. Cox B, Chhabra A, Adler M, Simmons J, Randlett D. Cannabinoid hyperemesis syndrome: case report of a paradoxical reaction with heavy marijuana use. Case Rep Med. 2012;2012:757696.

Follow us on our website: www.occpweb.org Facebook: www.facebook.com/OCCPclinicalpharmacy Instagram: occp

New Drug Update

Review of Oliceridine for Treatment of Moderate-to-Severe Pain in a Hospital Setting

Sumaia Aqtash, BSPharm, PGY-1 Pharmacy Resident; Courtney Hochman, PharmD, BCPS, CACP

Western Reserve Hospital

Current guidelines recommend a multimodal approach for the treatment of postoperative pain.¹ Multimodal therapy involves using various techniques and medications with different mechanisms of action for pain management. Postoperative treatment is dependent on the type of surgical procedure, patient-specific characteristics, and treatment goals. Although opioid-sparing regimens are recommended and have shown to be effective in less invasive procedures, intravenous (IV) opioids remain a critical component for the treatment of moderate-to-severe post-surgical pain.¹

Oliceridine (Olinvyk[©]) is a new chemical opioid that was approved by the U.S. Food and Drug Administration (FDA) in August 2020. It is prescribed as a short-term IV drug to manage moderate-to-severe acute pain in adults that are not adequately treated by other IV opioids. Unlike other opioids that act on both the G-protein and beta-arrestin pathway, oliceridine is a G-protein selective mu-opioid agonist that provides greater analgesia with reduced respiratory and gastrointestinal adverse effects.^{2,3}

The most common side effects (>10%) included: nausea, vomiting, constipation, dizziness, headache, hypoxia, and pruritus.² Oliceridine carries a black box warning for addiction, abuse and misuse, life-threatening respiratory depression, and neonatal opioid withdrawal syndrome with prolonged use during pregnancy.^{2,3}

As with other opioids, oliceridine dosing regimens are patientspecific and require titration to provide adequate pain relief. Based on the clinical studies, initial IV bolus dosing is 1 to 2mg with supplemental doses of 1 to 3mg every 1 to 3 hours, as needed. It is recommended that the cumulative daily dose not exceed 27mg as doses greater than 27mg have shown to cause QTc prolongation. Initial data indicates that 1mg of oliceridine is equivalent to 5mg of IV morphine. Due to the risk of withdrawal symptoms, oliceridine should not be discontinued abruptly, but rather tapered down slowly. The rate and duration of the taper is primarily dependent on the patient's condition and response. An advantage of oliceridine is that it doesn't require dose adjustment for renal impairment.^{3,4}

Oliceridine is primarily metabolized by the liver, mainly by CYP3A4 and CYP2D6, which may result in clinically significant drug interactions upon concomitant administration with moderate-to-strong CYP3A4 or CYP2D6 inducers or inhibitors. Depending on the situation, dose adjustment may be warranted.^{3,4}

FDA approval of oliceridine was based on the results of phase 3 clinical trials (see next page) which evaluated the safety and efficacy of the drug in 1,535 patients with moderate-to-severe pain.³ All 3 studies suggest that oliceridine provides improve-

ments in respiratory safety and the incidence of nausea and vomiting compared to morphine.^{5,6,7}

Overall, oliceridine has shown a favorable benefit-risk profile and is a valuable treatment option when managing pain inadequately controlled by other IV opioids. Its novel mechanism of action makes oliceridine a good option for patients with a history of opioid-induced adverse effects.⁴ As of now, no cost data studies are available. The FDA approval of oliceridine will result in the general trend of discovering opioids with greater Gprotein selectivity due to an improved therapeutic index owning to increased analgesia and decreased adverse effects.

References:

- Chou R, Gordon DB, de Leon-Casasola OA, et al. management of postoperative pain: a clinical practice guideline from the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' Committee on Regional Anesthesia, Executive Committee, and Administrative Council [published correction appears in J Pain. 2016 Apr;17(4):508-10]. J Pain. 2016;17(2):131-157. doi:10.1016/ j.jpain.2015.12.008
- FDA news: issue 25, august 2020. (2020, August). American Society for Clinical Pharmacology. https://www.ascpt.org/Resources/ASCPT-News/ View/Articleld/25154/FDA-News-Issue-25-August-2020
- FDA approves new opioid for intravenous use in hospitals, other controlled clinical settings. (2020, august 8). U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-approvesnew-opioid-intravenous-use-hospitals-other-controlled-clinical-settings
- FDA Advisory Committee document: oliceridine. meeting of the anesthetic and analgesic drug products advisory committee. (2018, October 11). U.S. Food and Drug Administration. https://www.fda.gov/media/121230/ download
- Viscusi ER, Skobieranda F, Soergel DG, Cook E, Burt DA, Singla N. APOLLO-1: a randomized placebo and active-controlled phase III study investigating oliceridine (TRV130), a g protein-biased ligand at the μ-opioid receptor, for management of moderate-to-severe acute pain following bunionectomy. *J Pain Res.* 2019;12:927-943. Published 2019 Mar 11. doi:10.2147/ JPR.S171013
- Singla NK, Skobieranda F, Soergel DG, et al. APOLLO-2: a randomized, placebo and active-controlled phase III study investigating oliceridine (TRV130), a g protein-biased ligand at the μ-opioid receptor, for management of moderate to severe acute pain following abdominoplasty. *Pain Pract.* 2019;19(7):715-731. doi:10.1111/papr.12801
- Bergese SD, Brzezinski M, Hammer GB, et al. ATHENA: a phase 3, openlabel study of the safety And effectiveness Of oliceridine (TRV130), A gprotein selective agonist at the μ-opioid receptor, in patients with moderate to severe acute pain requiring parenteral opioid therapy. J Pain Res. 2019;12:3113-3126. Published 2019 Nov 14. doi:10.2147/JPR.S217563

New Drug Update continued on page 10

New Drug Update

Review of Oliceridine for Treatment of Moderate-to-Severe Pain in a Hospital Setting

Sumaia Aqtash, BSPharm, PGY-1 Pharmacy Resident; Courtney Hochman, PharmD, BCPS, CACP

Western Reserve Hospital

New Drug Update continued from page 9

Phase 3 Clinical Trials			
Study	Study Design	Treatment Regimen(s)	Outcomes
Randomized	, multicenter, doub	le-blinded study	
APOLLO 1 ⁵ (N= 389)	48 hours post bunionectomy	 <u>IV Oliceridine:</u> o 1.5mg loading dose o 0.1, 0.35 and 0.5mg demand dose <u>IV Morphine:</u> o 4mg loading dose o 1mg demand dose 	 Superior to placebo in providing rapid analgesia for the pain relief for oliceridine 0.1, 0.35, and 0.5mg demand dose regimens (61%, p = 0.029; 76.3%, p < 0.0001; and 70%, p = 0.0004) 0.35mg and 0.5mg doses are non-inferior
APOLLO 2 ⁶ (N=401)	24 hours post abdominoplas- ty	• <u>IV Placebo:</u> Volume- and time-matched treatment	to morphine for pain relief. • Equi-analgesic dose groups of 0.35 and 0.5mg showed a favorable safety and tolera- bility profile regarding respiratory (oliceridine 0.35mg regimen: 21.5%; olicer- idine 0.5mg regimen: 22.5%; morphine: 26.8%) and gastrointestinal adverse effects compared to morphine.(0.1mg: 40.8%, 0.35mg: 59.5%, and 0.5mg: 70.9% compared to morphine: 72.4%).
Open label st	tudy		
ATHENA ⁷ (N= 768)	Surgical and medical pa- tients	 <u>Clinician-administered bolus dosing:</u> o 1-2mg initial dose o 1mg supplemental dose PRN o Subsequent doses 1-3mg every 1-3 hours PRN <u>In settings where rapid analgesia is targeted</u>: o 1-3mg initial dose o 1-3mg supplemental doses every 5 minutes PRN o subsequent doses 1-3mg every 1-3 hours PRN <u>PCA regimen:</u> o 1.5mg loading dose, 0.5mg demand dose, 6-minute lockout interval o 1mg supplemental dose PRN 	 Favorable safety and tolerability profile seen with a larger, more diverse patient pop- ulation including elderly, obese, and renally impaired. The most common AE observed were nau- sea (31%), constipation (11%), and vomiting (10%). AEs were mostly of mild or moderate se- verity and considered possibly or probably related to oliceridine in 33% of patients. There were no differences observed in the overall incidence of AEs with administration via bolus (63%) or PCA (65%).