You may preview your newsletter as many times as you like.

Your next publish window will be from **06-Apr-16** to **20-Apr-16**. Click on the Production Calendar tab above for details.

### Headlines

#### VSHP News
- Call for Candidates to VSHP Board
- VSHP Spring Seminar, April 8-9, 2016
- Clinical Article

#### ASHP News
- Pharmacy Students Push for Provider Status on Capitol Hill
- FDA Addresses ASHP Concerns in Pre-Published Guidance
- Companies Use Value-Based Pricing for Single-Source Off-Patent Drugs
- ASHP Expresses Major Concerns with Proposed Revisions to Chapter <797> Standards, Offers Recommendations
- Baxter Recalls 0.9% Sodium Chloride Irrigation Lot G120162

#### Pharmacy News
- Health-System Pharmacists Empower the Team
- Hospitals’ Medicine Mistakes Spike, but More Mysteries Revealed
- UA College of Pharmacy Developing Dry Powder Inhalers to Treat Pulmonary Diseases
- Drug Shortages Forcing Hard Decisions on Rationing Treatments
- Embracing Pharmacy Care Management for High-Value Care Delivery
- New ‘Smart Pill Bottle’ Knows When You’ve Taken Your Medication
- New Study Highlights Risks of Combining Benzodiazepines and Opioids
- ‘Adherent’ Patients May Not be Better Than ‘Non-Adherent’ Peers at Taking Their Medication
- Program Helps Patients Improve Medication Adherence
- Wisconsin Pharmacies Will Pilot Making Prescription Bottles Easier to Read
- RxSafe, Datarithm Team to Streamline Pharmacy Inventory Management

### Calling for Candidates to VSHP Board

The 2016 VSHP Committee on Nominations is pursuing members who wish to get or stay active and involved in VSHP. These candidates should exhibit qualities of leadership, vision and professional awareness that will sustain the enterprising and pioneering spirit that has characterized VSHP.

The offices of President-elect, Secretary and Board Member at Large are included in this election cycle. Nominees must be a pharmacist member of VSHP.


Additionally, VSHP is accepting nominations for Regional President-elect for each of the 7 VSHP Regions. This person will serve as President-elect for your region from July 2016 to July 2017 and succeeds

---

to the office of regional President from July 2017 to July 2018.

All interested VSHP members who would like to self-nominate or nominate a colleague for any VSHP or Regional office are encouraged to do so using the nominations link below by April 8th. Although any member may nominate a pharmacist for VSHP office, VSHP bylaws state that only pharmacist members may vote in the election. Ballots will be administered electronically after nominees have accepted and been verified.

Candidates for state office will be vetted by the VSHP Nominations Committee.

If you have any questions regarding this process, please contact us at contact@vshp.org.

Follow this link to nominate:
Nominate Here

---

**VSHP Spring Seminar, April 8-9, 2016**

The 2016 VSHP Spring Seminar will be held April 8-9, 2016 at The Westin Virginia Beach Town Center.

To Register for the Spring Seminar

To Register for Precepting 101 on Thursday afternoon - no charge for attending this program

To Register for the MTM Certificate Program Sunday April 10 - there is a separate fee to attend this program

Hotel Reservations

VSHP room block rate is $145 per night single/double. To make your hotel reservation call 800-937-8461. Room block cut-off is March 8, 2016.
Clinical Article

New Drug Update: Cariprazine (Vraylar™)

Jennifer Alastanos, PharmD and Ericka Crouse, PharmD, BCPP, CGP, FASHP; Virginia Commonwealth University Health System

Cariprazine (Vraylar™) is a second generation antipsychotic approved by the US Food and Drug Administration in September 2015 for schizophrenia and manic or mixed episodes of bipolar I disorder. Cariprazine is a partial agonist at central dopamine, D₂ and D₃ receptors and serotonin, 5-HT₁A receptors, and an antagonist at 5-HT₂A receptors.¹,² Cariprazine is the third dopamine receptor partial agonist to be approved, but the first with higher affinity for D₃ versus D₂ receptors.¹-⁴ The D₃ receptor is thought to play a role in regulating mood and cognition. Higher affinity for the D₃ receptor may potentially target negative symptoms and cognitive impairment, but it is currently unknown if it offers any clinical benefit.²-⁴ The other available second generation antipsychotic partial agonists are aripiprazole (Abilify™) and brexpiprazole (Rexulti™).²

Cariprazine was superior to placebo in three, 6-week clinical trials for schizophrenia. Two of the clinical

trials included an active control arm (aripiprazole or risperidone) and a fixed dose of cariprazine. The third trial was a phase III, multicenter, randomized, double-blind, placebo-controlled, parallel group, fixed/flexible-dose study. Cariprazine 3-6 mg/day and 6-9 mg/day were compared to placebo for 6 weeks in patients with an acute exacerbation of schizophrenia. The primary efficacy endpoint was the change from baseline to week 6 in Positive and Negative Syndrome Scale (PANSS) total score. The least squares mean difference (LSMD) and 95% confidence interval (CI) versus placebo for PANSS total score change at week 6 was statistically significant for both cariprazine groups versus placebo (LSMD [95% CI]: 3-6 mg/day group -11.3 [-11.3 to -2.4], p = 0.003; 6-9 mg/day group -9.9 [-14.5 to -5.3], p < 0.001). Cariprazine was superior to placebo in three, 3-week flexible dose clinical trials for manic or mixed episodes of bipolar I disorder. In a phase III, multicenter, randomized, double-blind, placebo-controlled, parallel group, fixed/flexible-dose study cariprazine doses 3-6 mg/day and 6-12 mg/day for 3 weeks were compared to placebo in patients meeting DSM-IV-TR criteria for acute manic or mixed episodes associated with bipolar I disorder. The primary efficacy parameter was change from baseline to week 3 in Young Mania Rating Scale (YMRS) total score. The LSMD for change from baseline to week 3 in YMRS total score was statistically significant for both cariprazine groups versus placebo (LSMD [95% CI]: 3-6 mg/day group -8.4 [-8.4 to -3.8], p < 0.001; 6-12 mg/day group -5.9 [-8.2 to -3.6], p < 0.001).

Cariprazine carries the same warnings as other antipsychotics, including but not limited to increased mortality and cerebrovascular adverse reactions in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, tardive dyskinesia, and seizures. A unique warning to cariprazine is late-occurring adverse reactions which may first appear several weeks after initiating therapy due to accumulation of cariprazine secondary to a long half-life. Cariprazine has two active metabolites, didesmethyl cariprazine and desmethylcariprazine. The half-life of cariprazine is 2-4 days; however didesmethyl cariprazine is pharmacologically equipotent to cariprazine and has a half-life of 1-3 weeks.

Metabolic changes also exist with cariprazine, including warnings for hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. In the 6-week schizophrenia trials the mean weight change at endpoint was +0.8 to 1 kg in cariprazine groups compared to +0.3 kg in placebo. In the 3-week bipolar I disorder trials the mean weight change at endpoint was +0.5 to 0.6 kg in cariprazine groups compared to +0.2 kg in placebo. Cariprazine did not prolong the QTc interval at doses three-times the maximum recommended dose. The most common adverse effects in the 6-week schizophrenia trials associated with cariprazine were extrapyramidal symptoms, akathisia, insomnia, and headache. In the 3-week bipolar I disorder trials the most common adverse effects in cariprazine groups were extrapyramidal symptoms, akathisia, headache, and nausea. Although rare, in long-term uncontrolled schizophrenia (48-week) and bipolar I disorder (16-week) trials, cataracts developed in 0.1% and 0.2% of patients, respectively.

An initial starting dose of cariprazine 1.5 mg is recommended with titration to 3 mg on day 2. Further dosage adjustments can be made in 1.5 to 3 mg increments based on response and tolerability to a maximum daily dose of 6 mg. Although studied up to 9 mg in schizophrenia and 12 mg in bipolar disorder, doses exceeding 6 mg were determined not to have significant additional benefit. The medication undergoes hepatic metabolism by cytochrome P450 (CYP) enzymes, primarily CYP3A4 and to a lesser extent by CYP2D6. The dose must be reduced by 50% for patients on a strong CYP3A4 inhibitor. The medication should be avoided in patients on a CYP3A4 strong inducer (e.g., carbamazepine), patients with severe hepatic impairment, or patients with a creatinine clearance less than 30 mL/min. Cariprazine is also undergoing investigation for the treatment of bipolar I depression and as an adjunctive treatment for major depressive disorder, but is not currently approved for either indication.

References
**Pharmacy Students Push for Provider Status on Capitol Hill**

2/26/2016

Nearly 50 students visited 31 congressional offices on Capitol Hill earlier this month as part of ASHP's Student Advocate Training & Legislative Day. The two-day conference, also known as SSHPTakesDC, gives student pharmacists hands-on experience in how to directly affect public policy.

During meetings at the U.S. Capitol with members of Congress and legislative staff, the students made the case for provider status legislation, the Pharmacy and Medically Underserved Areas Enhancement Act (H.R.592 and S.314), by emphasizing how the pharmacy school curriculum and postgraduate residency training prepare future practitioners to be patient care providers.

Read More

**FDA Addresses ASHP Concerns in Pre-Published Guidance**

2/26/2016

The Food and Drug Administration (FDA) today announced the availability of a guidance for industry entitled "Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act — Compliance Policy."

The guidance specifically addresses concerns raised by ASHP and its members over the ability of hospitals to supply first responders with medications in anticipation of emergent use or specific patient need.

Read More

**Companies Use Value-Based Pricing for Single-Source Off-Patent Drugs**

[March 15, 2016, AJHP News]

Cheryl A. Thompson

BETHESDA, MD 25 Feb 2016 - The behind-the-scenes decisions on prices for single-source off-patent drugs came center stage on February 4 when two company executives explained business strategies to the House Committee on Oversight and Government Reform.

Valeant Pharmaceuticals International, Inc.’s Howard B. Schiller and Turing Pharmaceuticals’ Nancy Retzlaff faced a panel of congressional representatives who took turns questioning the executives on their companies' conduct.

Read more

**ASHP Expresses Major Concerns with Proposed Revisions to Chapter <797> Standards, Offers Recommendations**

2/22/2016

A number of proposed changes to the U.S. Pharmacopeial Convention (USP) General Chapter <797> Pharmaceutical Compounding - Sterile Preparations standards are incompatible with the medication-use process in patient care environments, ASHP stated in comments submitted to a USP expert panel earlier this month.

In its comment letter, ASHP points out that many of the new requirements are more appropriate for making drugs from bulk chemicals in compounding pharmacies or outsourcing facilities than for preparing medications for administration in patient care settings. The letter urges the expert panel to revise the proposals to better meet the urgent and unpredictable demands of the typical acute patient care setting.

Read more
Baxter Recalls 0.9% Sodium Chloride Irrigation Lot G120162

Cheryl A. Thompson

BETHESDA, MD 19 Feb 2016 - Baxter International Inc. on Wednesday announced the recall of lot G120162 of the company's 500-mL 0.9% Sodium Chloride Irrigation product because an insect was found in one bottle of solution from the lot.

The product's labeling states that the solution is "for irrigation only." The company said the solution may be used to flush or rinse medical equipment, such as catheters.

Read more

Pharmacy News

Health-System Pharmacists Empower the Team

Drug Topics (02/10/16) Vecchione, Anthony

Health-system pharmacists are increasingly involved in patient care and interact regularly with physicians, nurses, and other caregivers. They evaluate trends in medication use and physician prescribing, develop guidelines for medication use, and implement and maintain drug distribution systems. In some hospitals, they provide specialized services in areas such as pediatrics, oncology, infectious diseases, nutrition support, and drug information. As patient safety experts, they are responsible for the automation systems that control drug distribution. In collaboration with nursing, they help to ensure that patients receive the right medication, in the correct form and dosage, at the right time, in order to prevent adverse events. "Hospital pharmacists have long embraced the roles that practice standards, residency training, credentialing and privileging, and specialty certification play in achieving optimal patient care outcomes," says Kasey K. Thompson, PharmD, MS, MBA, vice president, ASHP Office of Policy, Planning, and Communications. Thompson notes that pharmacy technician education, training, and certification, along with the enhanced use of information technology, have also played important roles. "These advancements and others in hospitals have served as examples for other practice settings, many of which are now seeking to adopt similar pharmacy practice models," Thompson says. As the role of the health-system pharmacist continues to expand beyond clinical duties, the pharmacy executive, a relatively new position, is also gaining ground. According to ASHSP, it behooves hospitals and health systems to have a pharmacy executive responsible for the strategic planning, design, operation, and improvement of the organization’s medication management system.

Hospitals' Medicine Mistakes Spike, but More Mysteries Revealed

Minneapolis Star Tribune (02/19/16) Olson, Jeremy

The Minnesota Department of Health has identified 4 deaths and 10 serious injuries caused by medication mix-ups at hospitals statewide during the 12 months ended October 6. The tally reflects the highest total in more than a decade of "adverse event" reporting there, despite greater use of computerized order entry and robotic drug dispensers. "There are many transition points" in prescribing," acknowledges Rahul Koranne, MD, chief medical officer for the Minnesota Hospital Association. "The medicine is ordered by the physician, so there is room for human error there. The medication is then checked off by the nurse ... and evaluated by the pharmacist." However, collecting error data has helped to expose specific weak spots—showing blood thinners and cardiac drugs to be particularly problematic, along with medication checks and changes following patient discharge. While the report found that monitoring and recordkeeping systems can backfire by alerting patients too often for non-urgent matters, some hospitals have had success with programs that post pharmacists in the emergency room, where they interview patients and review prescription histories. The visits often lead to adjustments in patients' drug regimens.

UA College of Pharmacy Developing Dry Powder Inhalers to Treat Pulmonary Diseases

News-Medical.Net (02/24/16)

Research recently published in Expert Opinion on Drug Delivery details the development of dry powder inhalation aerosols to treat and prevent pulmonary diseases. The report, by University of Arizona College of Pharmacy assistant professor Heidi M. Mansour, discusses currently available dry powder inhalers for inhalable powder drug formulations used in the treatment of COPD, asthma, and pulmonary infections. Mansour says delivering drugs to the lungs is the best method of treatment, but there are a variety of complications involved. "The lung is the organ of life that we're targeting, so there are added regulations and added safety limits that we have to work within," she says.
Drug Shortages Forcing Hard Decisions on Rationing Treatments
New York Times (01/29/16) Fink, Sheri

In recent years, shortages of a wide variety of drugs have become increasingly common in American medicine. The American Society of Health-System Pharmacists currently lists inadequate supplies of more than 150 drugs and therapeutics, for such reasons as manufacturing problems and federal safety crackdowns. The rationing that results from such shortages has been largely hidden from patients and the public. Medical institutions across the country have faced choices about who gets drugs. Some institutions have formal committees that include ethicists and patient representatives; in other places, individual physicians, pharmacists, and drug company executives decide which patients receive a needed drug—and which do not. Marc Earl, a Cleveland Clinic pharmacist, says children are not favored over adults during chemotherapy shortages. But at other hospitals, they have been, because of their potentially longer life span or because they sometimes require smaller doses of a drug. At Cleveland Clinic, decisions about conserving, substituting, and allocating scarce drugs typically are made by small groups of doctors and pharmacists.

Embracing Pharmacy Care Management for High-Value Care Delivery
Drug Store News (02/12/16) Biczak, Laureen

Pharmacists have played a greater role in clinical care in recent years, thanks to two key trends. Medication adherence and the rising cost of generic and brand-name drugs have thrust pharmacists into the clinical spotlight and created a need for a multi-pronged approach to care. Non-adherence costs the United States about $290 billion each year, with only 50 to 70 of every 100 prescriptions being filled by patients, according to industry statistics. Only 25 to 30 of those are properly taken. These numbers can put a strain on value-based goals, so pharmacy care management has become a tool to address the issue. This management allows patients to receive consultation immediately after receiving a medication, which permits the pharmacist to evaluate the drug's potential effect on a patient and educate the patient on how to properly take the drug. "Pharmacies that capitalize on the unique knowledge base and expertise that [pharmacists] bring to care delivery can have greater success in moving the needle on outcomes and performance in the value-based health care landscape," writes Laureen Biczak, medical director of Goold Health Systems, a Change Healthcare company.

New 'Smart Pill Bottle' Knows When You've Taken Your Medication
ABC7Chicago.com (02/08/16) Fleischer, Tim

A "smart pill bottle" from AdhereTech alerts patients to when they have not taken their daily medications. "Patients just aren't taking their meds," said AdhereTech CEO Josh Stein. "It's one of the biggest problems in health care." The smart bottle signals a blue light and sounds an alarm when a person has missed his or her medication, sends the information to the individual's health care provider, and even directs a message to the patient's phone. Stein and his partners are working with hospitals to offer the bottles to patients taking expensive medication, where each dose is especially valuable. AdhereTech is also working with pharmacies to provide the technology for free and for use in clinical trials.

New Study Highlights Risks of Combining Benzodiazepines and Opioids
Pain Medicine News (02/10/2016) Holzman, David C.

The risk of overdose from taking opioid analgesics at the same time as benzodiazepines is four times the risk from taking opioids by themselves, according to new research. The study used VA documentation and the National Death Index to identify 422,786 veterans prescribed opioids for nonterminal cancer pain, about a quarter of whom also were on benzodiazepines. Approximately 2,400 people in the study sample suffered a fatal overdose, and about one-half of them were patients taking both drugs. "If you are going to prescribe benzodiazepines [to people on analgesic opioids], you should understand that there may be an increased risk of overdose, and you should consider what disorder you are attempting to treat," said coinvestigator Tae Woo Park, MD, of Brown University. "Typically, benzodiazepines are prescribed for anxiety disorders and insomnia, and these are pretty common in patients with pain problems. You want to ensure that you are prescribing in an evidence-based manner, and carefully weigh the risks and benefits of treatment." Park also identified high opioid doses, a history of mental health and/or substance abuse problems, and having more than one doctor prescribing opioids or more than one pharmacy filling them as other warning signs of high risk for overdose.

'Adherent' Patients May Not be Better Than 'Non-Adherent' Peers at Taking Their Medication
News-Medical.net (02/16/2016)

According to researchers the Universidad Miguel Hernández (UMH) in Spain, patients who are considered "adherent"—those who pick up their prescriptions each month—are not statistically any better than "non-
Program Helps Patients Improve Medication Adherence

Rapid City Journal (SD) (02/06/16) Gahagan, Kayla

Approximately 50% of patients do not take their medications as prescribed, according to Prescriptions for a Healthy America, and at least 125,000 Americans die each year as a result of poor medication adherence. A new program from the Medicine Shoppe aims to help, enabling patients with multiple medications to sync all of their medications to be picked up at the same time and sending a reminder the day before they are ready. Curt Rising, owner and pharmacist at the Medicine Shoppe, said that "on their own, patients typically fill meds 6 to 8 times a year," but with this program, patients are "filling 11 to 12 times a year." Rising said the patients’ relatives are often relieved when the patient receives a med box to help organize medications, or they use a program such as med sync. Other ways to help increase adherence include setting alarms, using cellphone apps designed for prescriptions, and writing reminders on a calendar. Dana Darger, director of pharmacy at Rapid City Regional Hospital, said the best thing a patient can do is sit down with their pharmacist and work out a schedule for medications.

Wisconsin Pharmacies Will Pilot Making Prescription Bottles Easier to Read

Wisconsin Public Radio News (02/15/16) Mills, Shamane

In Wisconsin, 46 pharmacy locations are participating in a campaign to boost prescription adherence by making medicine bottles easier to read and understand. Based on recommendations from the nonprofit U.S. Pharmacopeia Convention, the 2-year pilot program will include more white space and enlarged print on labels; use numerals instead of spelling numbers out; avoid type in all capital letters, which is more difficult to read; and be more specific about what the medication treats and when to take it. "One of the challenges that we have with current labels is that sometimes the most important things are not the things that are emphasized most," acknowledges Steve Sparks of Wisconsin Literacy, noting that pharmacy logos or prescribing doctors' names often claim the most space. He says pharmacies report that patients, especially those with multiple prescriptions, often ask for additional information to be written on their medicine label. The new standards, he says, will benefit all patients but older adults in particular as well as those with poor reading skills.

RxSafe, Datarithm Team to Streamline Pharmacy Inventory Management

Drug Store News (02/11/16) Salazar, David

In an effort to streamline inventory for pharmacy owners, pharmacy automation company RxSafe and inventory software company Datarithm are entering into a partnership. RxSafe’s real-time inventory combined with Datarithm’s software, which delivers optimized order points, can quickly identify surpluses and offer pharmacies solutions for handling them. "The result is a game-changing model that eliminates cycle-counting, frees up cash, and allows pharmacies to focus on patient care and services," said William Holmes, RxSafe president and CEO. Datarithm has also declared its eagerness to work with RxSafe: "Their RxSafe 1800 System, and all that it does, combined with Datarithm’s customizable Rx inventory software, and all it does, makes for a very flexible, powerful, and automated solution," said Datarithm VP sales and marketing Dan Sullivan.