BOLSTER ADHERENCE p20 / BATTLE BURNOUT p27 / 6 TECHNOLOGIES p30

DIVERSIFY & PROSPER

How independents can navigate new services to boost 2019 revenue p12
Influenza Update
FROM THE EDITORS OF Drug Topics

Antivirals Advance in Options, Indications

As pharmacies, doctors’ offices, and hospitals fill up with patients with influenza-like symptoms, the CDC reports seasonal influenza activity remains elevated and is widespread in most parts of the United States, with at least 22 flu-associated pediatric deaths through mid-January.

“In the last few weeks, influenza has really picked up across the country,” says Pritish K. Tosh, MD, an infectious diseases specialist at the Mayo Clinic in Rochester, MN.

The Walgreens Flu Index reported Nebraska had the most flu activity in the week ending Jan. 26, followed by Kentucky, Mississippi, Texas, and Alabama. The index ranks the top markets and states for flu activity in the United States and Puerto Rico and is compiled using prescription data for antiviral medications used to treat flu across thousands of Walgreens and Duane Reade locations.

Which Antiviral?
This year’s top virus is the H1N1, but H3N2 viruses have been hitting the South-east United States particularly hard, too.

Tosh says the most commonly prescribed antiviral medication for flu treatment—oseltamivir phosphate (Tamiflu) appears to be working against the H1N1 virus.

“So far the CDC has not reported oseltamivir resistance,” Tosh tells Drug Topics, adding the CDC has not reported any resistant viruses this flu season.

The 2008 flu strain was resistant to oseltamivir, but that has not reoccurred, notes Andrew T. Pavia, MD, professor and chief of infectious diseases at the University of Utah in Salt Lake City. Pavia is on a committee of the Infectious Disease Society of America (IDSA) that has updated clinical practice guidelines for treating influenza.

“Resistance is an issue, but not a huge one yet,” says Pavia, senior author on the IDSA recommendations. “But it’s always out there as a threat.”

High levels of resistance to the antiviral drugs amantadine and rimantadine were seen with influenza A viruses

CONTINUED ON BACK

<table>
<thead>
<tr>
<th>Antiviral Agent</th>
<th>Activity Against</th>
<th>Recommended Age</th>
<th>Not Recommended for Use in</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral oseltamivir</td>
<td>Influenza A and B</td>
<td>Any age</td>
<td>N/A</td>
<td>Nausea, vomiting, headache. Postmarketing reports of serious skin reactions and sporadic, transient neuropsychiatric events</td>
</tr>
<tr>
<td>Inhaled zanamivir</td>
<td>Influenza A and B</td>
<td>7 and older</td>
<td>People with underlying respiratory disease (eg, asthma, COPD)</td>
<td>Risk of bronchospasm, especially with underlying airways disease; sinusitis, and dizziness. Postmarketing reports of serious skin reactions and sporadic, transient neuropsychiatric events</td>
</tr>
<tr>
<td>Intravenous peramivir</td>
<td>Influenza A and B</td>
<td>2 and older</td>
<td>N/A</td>
<td>Diarrhea. Postmarketing reports of serious skin reactions and sporadic, transient neuropsychiatric events</td>
</tr>
<tr>
<td>Oral baloxavir</td>
<td>Influenza A and B</td>
<td>12 and older</td>
<td>N/A</td>
<td>None more common than placebo in clinical trials</td>
</tr>
</tbody>
</table>

Source: CDC

TABLE Antiviral Medications Recommended for Treatment of Influenza

ES58629_DRTP0219_OS1.pgs 02.04.2019 17:36 UBM
Antivirals are an Important Part of New IDSA Flu Guidelines

Just in time for this flu season, the Infectious Diseases Society of America (IDSA) has issued updated recommendations for healthcare professionals for the diagnosis, treatment, prevention, and outbreak management of seasonal influenza. The new guidelines—the first update in 10 years—focus on three areas: adding groups to those at high risk for flu complications, recommending use of newer fast and accurate molecular tests to diagnose influenza, and prescribing antiviral medications for those at high risk even if they have been sick for more than two days.

Andrew Pavia, MD, professor and chief of infectious diseases at the University of Utah in Salt Lake City and part of the IDSA committee updating the guidelines, notes the last recommendations were released before the 2009 H1N1 epidemic. “Since 2008, we have really developed a lot of new evidence about when and where antivirals work,” Pavia tells Drug Topics. “It’s important to get the message out. They can be life-saving to those with high risk of complications. They are important to people with high risk whether they are hospitalized or not.”

The new guidelines include:

- **ADDITIONAL HIGH-RISE RISK GROUPS** Pregnant women and those who have given birth within the last two weeks are among those considered at high risk for flu complications and should be tested and treated as soon as possible. Others added to the high-risk groups include people who are morbidly obese, those with neurological and neurodevelopmental disorders, those with weakened immune systems, nursing home residents, and Native Americans and Native Alaskans, who had a higher mortality rate during the 2009 pandemic.

- **MOLECULAR TESTING** Using highly accurate molecular tests that give results in 15 to 60 minutes instead of rapid-influenza diagnostic tests (RIDTs) that produce false negatives in at least 30% of outpatients with flu.

Influenza Update

CONTINUED FROM FRONT

in past seasons. These two drugs are not effective against influenza B, so they are not recommended by the CDC this season, Pavia says.

Antiviral medications are most effective when taken within the first 48 hours after the start of flu symptoms such as fever, chills, cough, sore throat, runny or stuffy nose, muscle aches, and headache. In otherwise healthy patients, antivirals are not very useful if started more than 48 hours after onset of symptoms, Pavia says.

“But in hospitals, where illnesses last a lot longer, they’ve been given as late as five or seven days after onset,” he notes.

Oral oseltamivir can be prescribed for a patient of any age suffering from influenza A or B strain. Adverse effects can include nausea, vomiting, and headache, and there have been some reports of serious skin reactions and sporadic transient neuropsychiatric events. In adults, the recommended dose is 75 mg twice a day for five days. For children over age 1, the dose varies by weight. Dosage can range from 30 mg twice daily for a child weighing 15 kg or less to a 75-mg dose twice daily for a child weighing more than 40 kg.

Tosh says oseltamivir reduces symptoms in otherwise healthy people, who are unlikely to have complications from influenza, and helps prevent severe outcomes in those with underlying conditions.

Inhaled zanamivir (Relenza) also works well against influenza A and B and can be used to treat those age 7 and older who do not have respiratory diseases like asthma and COPD, Pavia says. It should not be prescribed to those with allergies to milk proteins. Adverse reactions include bronchospasm, sinusitis, and dizziness. Some serious skin reactions and sporadic transient neuropsychiatric events were also reported. Treatment of two 5-mg inhalations lasts for five days. It’s primarily used for hospitalized patients and others who can’t swallow oral oseltamivir, he says.

Intravenous peramivir (Rapivab) can be used for influenza A and B in patients 2-years-old and older and is often used in hospital settings. For children age 2 to 12, one 12-mg/kg dose up to 600 mg is given via IV infusion for at least 15 minutes. Those age 13 and older should be given one 600 mg for at least 15 minutes. The most common side effect is diarrhea.

This year, pharmacists are seeing prescriptions for a new antiviral, baloxavir marboxil (Xofluza). It is for treatment of uncomplicated flu in people 12-years-old and older. It is not recommended for pregnant women, breastfeeding mothers, those with chronic illnesses, or hospitalized patients because it has not been studied in those groups.

Baloavix is a one-dose tablet that can be used for influenza A and B in patients 12 and older who weigh at least 40 kg. Those weighing 40 kg to 80 kg should get one 40-mg dose, and those above 80 kg should receive one 80-mg dose. The most common adverse reactions are diarrhea and bronchitis.

Pavia notes that baloxavir’s side effects, which can also include headaches, are consistent with flu symptoms, so pharmacists need to advise patients and families of that.

He says pharmacists need to be familiar with side effects of all antivirals so they can be shared with patients.
THINK FIRST BEFO COM

Single prescription compounding made QUICK & EASY.

CONVENIENT + COMPLIANT + CONSISTENT

CutisPharma
Transforming Medicine through Innovation®
PRODUCT ANNOUNCEMENT

INTRODUCING FIRST KITS

two additions to our family of products.

EXPECTED Release

JANUARY 2019
FIRST Metoprolol

MARCH 2019
FIRST Atenolol

To learn more about our family of kits or specific product information, visit WWW.CUTISPHARMA.COM or call us at 1-800-461-7449, ext 119.
NRx® allows you to be all the things you ever wanted to be - for all the right reasons.

As a community pharmacist, we know you have many responsibilities. NRx helps you run your pharmacy more efficiently with e-Care plans for better reimbursement rates and customized medication therapy management (MTM) options. As the most comprehensive pharmacy management system on the market, NRx gives you more time with your patients - and more time with your family.
Drug Topics
Voice of the Pharmacist

EDITORIAL ADVISORY BOARD

Michael Cohen, RPh, MS, S&F Pharm, USP Pharm, 7ASHP
President
Institute for Safe Medication Practices
Horsham, PA

Mary E. Ingualdi, RPh, MPH, ASHP
Strategic Customer Vice President BD
South Windsor, CT

Frederick S. Mayer, RPh, MPH
President
Pharmacists Planning Service Inc.
San Rafael, CA

David D. Pope, RPh, CDE
Chief of Innovation,
Co-Founder
Creative Pharmacist
Agoura, CA

Perry Cohen, PharmD, FAMCP
The Pharmacy Group LLC
Glastonbury, CT

Mohamed A. Jalloh, PharmD
Assistant Professor In Clinical Sciences
Touro University California College of Pharmacy
Vallejo, CA

Gene Memoli Jr., RPh, FASCP
Director
Customer Development,
Omnicare
Cheshire, CT

Brian Ronig, RPh, MBA
Vice President
Corporate Pharmacy Director
Supply Chain
Adventist Health System
Annawan Springs, FL

David J. Fong, PharmD
Retail Pharmacy Consultant; Former Senior Executive for Community Chain Stores
Danville, CA

James Jorgenson, RPh, MS
CEO & Board Chairman
Visante, Inc.
St. Paul, MN

Marvin R. Moore, PharmD
Pharmacy Manager & Co-Owner
The Medicine Shoppe/Pharmacy Solutions Inc.
Two Rivers, WI

Lisa M. Holle, PharmD, BCDP, FHOPA
Associate Clinical Professor
UCSan Diego School of Pharmacy
Storrs, CT

Debbie Mack, BSPharm, RPh
Director
Pharmacy Regulatory Affairs
Walmart Health and Wellness
Bentonville, AR

Mark Neuenschwander, President
The Neuenschwander Company
Bellevue, WA

CONTENT
EXECUTIVE EDITOR David Frabotta
440-826-2822 | david.frabotta@ubm.com

MANAGING EDITOR Valerie DeBenedette
203-533-7024 | valerie.debenedette@ubm.com

ASSOCIATE EDITOR Drew Boxler
440-891-2630 | drew.boxler@ubm.com

DESIGN
DESIGN DIRECTOR Robert McGarr

PUBLISHING AND SALES
VP, SENIOR MANAGING DIRECTOR,
UBM LIFE SCIENCES GROUP
Thomas W. Ehardt
732-346-3071 | william.mulderry@ubm.com

VP GROUP PUBLISHER William Mulderry
PUBLISHER, BUSINESS DEVELOPMENT
Margo Ullmann
973-978-5964 | margo.ullmann@ubm.com

DIRECTOR, NATIONAL ACCOUNTS PRINT/DIGITAL
Dan Gallo
203-523-7037 | daniel.gallo@ubm.com

ACCOUNT MGR., PRINT/DIGITAL
Patrick Carmody
440-891-2621 | patrick.carmody@ubm.com

ACCOUNT MGR., RECRUITMENT
Joanna Shippoli
440-891-2615 | joanna.shippoli@ubm.com

SALES DIRECTOR, DIGITAL MEDIA
Don Berman

VICE PRESIDENT, MARKETING
Amy Erdman

permissions Jillyn Frommer
732-346-3007 | jillyn.frommer@ubm.com

reprints Licensing and Reuse of Content: Contact our official partner, Wright’s Media, about available usages, license fees, and award seal artwork at Advanstar@wrightsmedia.com for more information. Please note that Wright’s Media is the only authorized company that we’ve partnered with for Advanstar UBM materials.

PRODUCTION
PRODUCTION DIRECTOR Karen Lenzien
218-740-6371 | klenzen@hcl.com

AUDIENCE DEVELOPMENT
VP, MARKETING & AUDIENCE DEVELOPMENT
Joy Puzzo
DIRECTOR, AUDIENCE DEVELOPMENT
Christine Shappell
AUDIENCE DEVELOPMENT MGR.
Jessica Stariha
612-253-2039 | Jessica.Stariha@ubm.com

EDITORIAL MISSION: Drug Topics is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.

4 DrugTopics | FEBRUARY 2019 | DRUGTOPICS.COM
Pharmacists Are Best Suited to Improve Adherence

Despite numerous studies evaluating interventions to improve medication adherence and frameworks to understand barriers to adherence, approximately 50% of Americans are considered nonadherent to their chronic medication regimens. This can be because they are not taking their medications at all or are taking them at doses and/or times that are not recommended by their healthcare team. Either way, this is a critical issue that contributes to poor health outcomes and unnecessary healthcare expenditures.

Pharmacists can play a critical role in helping patients with medication adherence because they have a unique role in interacting with healthcare systems, insurers, and patients.

Factors that affect adherence include:

- Social and economic issues (unemployment, social support, needs for housing/food)
- Healthcare issues (multiple healthcare providers, insurance coverage)
- Condition-related issues (symptom severity, impact on quality of life)
- Therapy-related issues (perceived benefits/risks)
- Patient-related issues (knowledge, beliefs)

Understanding how these factors play a role is a key to assisting a patient to optimal adherence. Even if barriers are identified and addressed, they might change from refill to refill.

So, what can we do as the pharmacist? Taking the time to speak with the patient on a regular basis can allow us to learn about the patient’s situation and what could be done to address adherence barriers. By learning more about the individual patient, the pharmacist can anticipate potential medication issues and then discuss a plan with the patient. For example, if side effects develop, educating the patient about other treatment options or ways to mitigate side effects can alleviate their concerns. Educating the patient about the need to notify providers about any side effect before the next scheduled visit is important as well. Although this might seem like common sense to healthcare providers, many patients just stop their medication until the next visit, and it might be months between visits. By stressing the importance of open communication with their healthcare provider, this lapse in therapy can be prevented.

Whatever the barrier may be, it is important to note that continual assessment of adherence is necessary because the factors affecting the patient can frequently change. It is prudent to assess if new factors affecting medication adherence have arisen at each visit, and if therapeutic goals have changed.

Working with health insurers on behalf of the patient is another way to facilitate adherence. Although insurers often have rules on prior authorization, quantity limits, and such, discussing patient-specific situations with the insurer can help allow for exceptions. In some cases, pharmacists can justify payment for adherence services by collecting data on patient satisfaction, improvements in prescription claims-measured adherence, and impact on retail and prescription refill sales.

Pharmacists can offer patients tools to assist with adherence as well. Several medication apps are available. Calendars and notebooks have been used for decades. Newer methods such as smart vials, tablets with electronic tracking, rewards for filling refills on time, and texts from the healthcare team are all being evaluated, but none has proven successful in all settings. Thus, the pharmacist who can holistically assess these factors might be the most well suited to facilitate medication adherence. Take the opportunity to talk with your patients. You are uniquely positioned to make a real difference.

Lisa M. Holle, PharmD, BCOP, FHOPA, is associate clinical professor of pharmacy practice at UConn School of Medicine, Storrs, CT.
While high drug prices continue to come under fire by the government, healthcare professionals, consumers, and payers, a new report says net drug prices in the United States increased only an estimated 1.5% in 2018.

"Net price growth was below inflation in the wider economy in 2018, an occurrence expected to continue for the next five years," says a report from IQVIA Institute for Human Data Science, formerly the IMS Institute. The report is titled “The Global Use of Medicine in 2019 and Outlook to 2023: Forecasts and Areas to Watch.”

U.S. drug prices are projected to rise between 0% and 3% over the next five years, IQVIA says. Meanwhile, global drug spending reached $1.2 trillion in 2018, and is expected to top $1.5 trillion by 2023, up 50% from 2016, according to IQVIA. The United States and emerging markets will account for the majority of the drug spending increases in the next five years.

The number of new medicines launched is expected to increase from an annual average of 46 during the past five years to an average of 54 per year through 2023. The annual average spending in developed markets on new brands is expected to rise slightly to $45.8 billion in that time but will represent a smaller share of brand spending, IQVIA says.

The IQVIA report also noted that mobile apps, also called prescription digital therapeutics (DTx) are a new emerging treatment modality with indications and disease-specific treatment effectiveness claims in their prescribing labels. "Stakeholders are cautiously observing developments in DTx as this new modality could bring significant benefits but must be carefully weighed against the evidence for existing options. Where drug therapy alone has left unmet needs, particularly in the areas of behavioral health and cognition, these new technologies promise substantial advances," the report says.
**CVS Opening First Healthcare Concept Store**

As part of the many joint programs that CVS Health has launched since it acquired Aetna in 2018, CVS is opening the first of its healthcare concept stores this month.

The stores “will be a testing ground for a new retail engagement model that brings healthcare services to consumers in a more convenient, more accessible, and more customer-focused manner,” said Larry J. Merlo, president and CEO of CVS Health, speaking at the J.P. Morgan Healthcare Conference.

Concept stores, the first of which is opening in Houston, will provide “enhanced personalized prescription support” in pharmacies, according to Merlo. “We will use our data and analytics capabilities to provide actionable information through our pharmacy staff in an effort to improve patient care.”

The stores will also offer an expanded suite of healthcare services, including a “care concierge and other health and wellness support,” Merlo says.

MinuteClinics in the CVS concept stores will offer new clinical services, such as enhanced screenings for chronic disease and in-clinic phlebotomy.

CVS will add “new health and wellness categories” at the front of the store, “to focus on best of category assortments,” according to Merlo. The company is also piloting a specialized program to prevent hospital readmissions for Aetna members who are being treated for cardiovascular disease.

Starting sometime in the first quarter, Aetna care managers will be able to facilitate scheduling of MinuteClinic follow-up visits within 14 days after discharge, in cases where patients are unable to see their provider, Merlo adds.

---

**Little Time Off and Lack of Sleep Impact Pharmacy Residents’ Levels of Depression**

A multitude of factors—including a high number of hours worked and living with family—were associated with high levels of depressive symptoms in pharmacy residents, a new study says.

Published in the December 15, 2018, in the *American Journal of Health-System Pharmacy*, the study includes a nationwide online survey of pharmacy residents from 2015-2016.

Evan Williams, PharmD, assistant professor of pharmacy practice at the College of Pharmacy, Roseman University of Health Sciences in Nevada, and colleagues found that higher levels of depressive symptoms were linked to high levels of stress, a high number of hours worked, a high number of days between having a full 24 hours off duty, not having family within driving distance, and living with family.

Conversely, high levels of family support, an outpatient and/or clinic residency setting, supportive directors and preceptors, effective teaching methods, well-structured and organized programs, clear expectations of residents, having enough days off, and adequate amounts of sleep were associated with decreased reporting of depressive symptoms among pharmacy residents.

Since pharmacy residents are often tasked with weekend staffing, a typical schedule is 12 days on and two days off for residents in many smaller programs, Williams writes. “This schedule does approach the specified limits for consecutive days worked without a full 24 hours off, and our data suggest that longer periods without a full 24 hours off are associated with increasing levels of depressive symptoms.”

Pharmacy residents who reported getting adequate sleep reported depressive symptoms four to five times less frequently than those who said they were not. “Pharmacy residents and directors should be cognizant of sleep needs and ensure that an adequate amount of quality sleep is attained to improve resident well-being and prevent medical errors,” Williams writes.

---

**REPORT: Pharmacists Should Practice at Top of Professional License**

Pharmacy organizations are applauding a recent HHS report that states that pharmacists should practice at the top of their professional license—and be paid for those services.

The report acknowledges that pharmacists, advanced practice registered nurses, physician assistants, and other healthcare professionals can “safely and effectively provide some of the same healthcare services as physicians, in addition to providing complementary services.”

Unfortunately, scope-of-practice rules often “unnecessarily limit the services these ‘allied health professionals’ can offer, according to the report.

“For years, APhA has fought for the recognition of pharmacists as providers of quality patient care and the need to cover their services,” says APhA CEO Thomas E. Menighan, BSPharm, in a statement. “We’re grateful our role in healthcare is being recognized as a part of the solution to help Americans lead healthier lives—something our patients already know.”

However, APhA points out that Congress still needs to pass the Pharmacy and Medically Underserved Areas Enhancement Act (HR 592 /S 109), a bipartisan bill that would increase medically underserved Medicare beneficiaries’ access to healthcare through pharmacist-provided services. “Our approach to expanded access and patient-centered team-based care should be embraced by all,” Menighan says.

While the report acknowledges pharmacists’ vital role, some of the provisions in the new report could have a negative influence on patient choice and access to care, according to APhA. The organization “would like to work with the Trump administration on health care reform policies that balance patient access along with costs.”
**OTC/Coprescribing Could Increase Access to Naloxone**

New efforts from the FDA and HHS could help improve access to naloxone. The FDA says it will remove barriers and make it easier for drug manufacturers to develop over-the-counter naloxone.

To encourage manufacturers to enter the OTC naloxone market, FDA “designed, tested, and validated the key labeling requirements necessary to approve an OTC version of naloxone and make it available to patients. One of the key components for OTC availability is now in place,” says FDA Commissioner Scott Gottlieb, MD, in a statement.

In addition, HHS says that “clinicians should strongly consider prescribing or coprescribing naloxone [with opioids],” in a new guidance. “Data clearly indicate a significant persistent gap in our response—the infrequent coprescribing of naloxone to patients who are prescribed opioids and/or those who are at high risk of experiencing (or responding to) an opioid overdose. National data on patients to whom clinicians should consider co-prescribing naloxone show that less than 1% of these patients actually receive a naloxone prescription,” HHS says.

Pharmacists can provide risk education and increase dispensing rates of naloxone, when appropriate, Carlie Taylor, PharmD, associate director for strategic initiatives with NCPhA, tells Drug Topics. “There are currently several states that have standing orders for naloxone, so they are able to dispense it without obtaining a prescription from the physician.”

While coprescribing could increase the number of patients at risk of overdose gaining access to naloxone, it does not directly translate into codispensing, Taylor says. “There may be additional barriers such as price and product availability. Not all insurances cover naloxone, and if they do, the copay may not fall within the consumers’ budget. In addition, if all opioid users started filling naloxone it could lead to drug shortages.”

---

**Hispanic Pharmacists Form Organization**

A new organization for Hispanic pharmacists has formed and has the support from Walmart and CVS Health.

The National Hispanic Health Foundation (NHHF) has formed the National Hispanic Pharmacists Association (NHPA), to increase access to care for Hispanic communities across the country.

The organization was launched with support from Walmart, CVS Health, and the Pharmaceutical Research Manufacturers Association (PhRMA).

While Hispanics make up the largest ethnic minority (17.8%) in the United States, Hispanic pharmacists make up only 4.5% of the 342,000 employed pharmacists across the country, says NHHF in a statement.

“Given that by 2042, one out of four people living in the United States will be Latino, NHHF is excited to launch NHPA so that Hispanic pharmacists can develop programs and opportunities that can directly impact the health of Americans,” says NHHF President Elena Rios, MD, in the statement.

Maria M. Hearns-Rivas, PharmD, president of the NHPA Board of Directors, adds, “Through my experiences in clinical practice and in working with Spanish-speaking patients, I’m confident that the NHPA will help address the health disparities that Hispanics face in the United States.”

NHPA will start a scholarship program, develop professional and continuing education opportunities, and expand the organization through new corporate partners. NHPA also looks to create a mentorship program and regional student chapters to increase the number of Hispanic pharmacists in the future and further the organization’s outreach,” NHHF says.

---

**Opioid Prescribing in Children Should be Standardized**

Standardized opioid use guidelines for use in pediatric emergency departments need to be developed, according to a study.

The study of 69,152 emergency department visits found that opioid prescribing rates dropped in recent years, but region, race, age, and payment method were associated with differences in opioids prescribing. The study was published in December 2018 in JAMA Network Open.

White pediatric patients had a significantly increased likelihood of being prescribed an opioid compared with nonwhite patients, the researchers found. “For instance, white patients reporting abdominal pain were almost twice as likely to receive an opioid than their nonwhite counterparts,” the researchers write.

In addition, patients in the western region of the United States were significantly more likely to be prescribed an opioid, while patients in the Northeast had the lowest likelihood of an opioid being prescribed. “Factors affecting the regional variability in opioid prescribing in pediatric patients need to be further evaluated to better understand what may be driving the overall prescribing patterns in each region, particularly those with higher opioid prescribing rates,” the researchers write.

Christine Blank is a healthcare journalist and a frequent contributor to Drug Topics.
Tax Reform:

Pharmacies now may switch from accrual to cash accounting

The Tax Cuts and Jobs Act of 2017 (TCJA) made significant changes to the tax code. One of the noteworthy changes that will impact pharmacies is the option to change from the accrual accounting method to the cash accounting method.

What Is an Accounting Method? An accounting method is the method a taxpayer uses to compute income. It determines the timing of when income and deductions are recognized. The two overall accounting methods applicable to pharmacies are the accrual and the cash methods of accounting.

Accrual Versus Cash: The accrual method recognizes revenue when earned, such as when a prescription is adjudicated, and it recognizes expenses when incurred, such as when a purchase is made instead of when it is paid. The cash method of accounting recognizes revenues when the revenue is received and recognizes expenses when the expenses are paid. The key distinction between the two methods is simply the timing of when income and expenses are recognized.

Before TCJA, pharmacies were required to report on the full accrual method of accounting, unless exceptions were met. The TCJA changed the accounting method options available for pharmacies. Unless your prior three-year average gross revenues (gross receipts test) in the pharmacy exceed $25 million, pharmacies are now allowed (but not required) to report on the cash method of accounting instead of the accrual method. Owners with multiple pharmacies under common ownership, such as controlled groups, must aggregate revenues when determining the gross receipts test.

Inventory has its own set of rules under the accrual and cash methods of accounting. If you choose the cash method, the TCJA allows taxpayers to either treat inventories as nonincidental materials and supplies or conform to the taxpayer’s financial accounting treatment of inventories. There are complex issues outside the scope of this article with regard to inventory under the TCJA, so consideration should be taken with your tax professionals to navigate this area of tax law.

481(a) Adjustment: An IRS Form 3115 Change in Accounting Method will need to be filed with your tax return if you change accounting method. The accounting adjustment from the accrual method to the cash method is called a Code Section 481(a) adjustment. If the adjustment is negative (an expense), it can be deducted in the current tax year. If the adjustment is positive (income), it may be taken in year one or, if over $50,000, is spread over a four-year period.

Example: Assume a pharmacy has the following accrual balance sheet items: accounts receivable third-party of $300,000, accounts payable of $50,000, accrued payroll payable of $25,000, and accrued interest payable of $5,000. The pharmacy elects to report on the cash basis. An adjustment to remove these accounts from the balance sheet would be a negative 481(a) or expense of $220,000 ($300,000 - $50,000 - $25,000 - $5,000). This expense would be deducted in the current tax year and would decrease net income, and thus taxable income, of the pharmacy for the year. As you see, it results in significant tax savings!

Tax Planning is necessary to proactively plan and analyze these changes with an experienced tax advisor. Issues that relate to ownership basis and losses, potentially selling your pharmacy in the near term, and how this accounting change will affect your books and records are just some of the items to be considered. With careful planning, the potential tax savings for pharmacies under the TCJA are extraordinary, especially with the option to change accounting methods.
Forty pharmacists in 26 states won elections in November, including four in statewide or federal races.

In California, State Sen. Jeff Stone, PharmD, won reelection to his second term in the 28th District, which stretches from southwest Riverside County across the Coachella Valley to the Arizona border.

Stone opened the Temecula (CA) Pharmacy in 1983 and became involved in local politics as a small business owner and a champion of the business community.

During his rise through positions in Temecula’s government, county board positions, and eventually the state senate, he has supported legislation to reduce regulations imposed on large and small businesses, which he says are the backbone of California’s economy. He has been an outspoken supporter for the pharmacy profession and a public health advocate throughout his career.

For his advancement of the profession and public health in California, Stone will be recognized as the Pharmacist Planning Services Inc. (PPSI) Distinguished Person of the Year in March. He will receive the award at the annual meeting of the California Pharmacists Association.

PPSI is a nonprofit public health advocate that has helped organize The Great American Smoke Out, National Condom Week, and programs on birth control, hepatitis C, and medicinal cannabis.

Stone continues to own and operate a local business, Innovative Compounding Pharmacy, in La Quinta, CA.

DT: Community pharmacists are often driven by the people they serve. Was this mentality part of what drove you to public service?

Stone: When I opened my first pharmacy in 1983 in Temecula, I never imagined running for public office. It was only when I saw the impact that graffiti was having on my community that I decided to get involved in 1992.

I ran for City Council because I wanted our city to crack down on vandals who were responsible for graffiti, and the voters in that election agreed. I’m proud to say I won handily and the City of Temecula still has the strongest anti-graffiti ordinance in the country. I quickly realized the common denominator between being a pharmacist and an elected official is helping people.

DT: What are some of the hallmarks of pharmacy practice that helped prepare you for public service?

Stone: Being a pharmacist comes with many attributes, including the ability to study and retain complex health-related issues. What does that have to do with being an elected official? In order to be an effective elected official, one must have the discipline to study and understand new issues in order to then mitigate the problems or improve situations.

As an independent pharmacy owner, I know firsthand the impacts of government regulations that can help or hurt my business. As the owner of the pharmacy, I need to understand accounting, workers compensation, insurance, employee laws, etc., hence making me more sensitive to the governmental mandates and unneeded bureaucracy.

Understanding these laws helps make me a better elected official. Having a medical background gave me a strong foundation as a county supervisor with a county hospital and helps me now as...
As small business owners, how important is it for independent pharmacists to engage with state and local governments?

Stone: If members of our profession do not get elected to state legislatures or federal office, then we succumb to bad laws authored by people that do not fully understand what we do and the challenges we face. As one of the most educated, but underutilized healthcare professionals, we need people in office who can help expand our scope of practice in accordance with our exceptional educational attributes.

What advice would you give pharmacists who are considering public service? Is there a process for preparing yourself or methods that you’ve identified as essential to be successful?

Stone: Public service comes in many forms. It’s not just running for public office. I would encourage those with a passion to serve to become involved in their local Chambers of Commerce, their local Rotary Club, and to serve on various city boards and commissions. It is truly amazing how much a person can get done to change the way things are run if they just step up and get involved in a meaningful way.

My best advice can be summed up easily—get interested, get involved, show up, and work to change the things you believe need changing. You would be surprised how effective you can be if you just do these few simple things.

What are your top priorities for this term?

Stone: I will be once again attempting to pass legislation that expands the scope of pharmacists to independently treat disease in cooperation with a physician, as a way to ease the burden on our healthcare system. Additionally, I will be working with several of my colleagues to enact strong regulations over how pharmacy benefit managers operate in California.

PBMs are the least regulated part of the healthcare delivery system, and they should not be allowed to force pharmacies to lose money when filling prescriptions or to automatically claw back payments previously authorized. In addition to pharmacy-related legislation, I will also focus on economic development, public safety, and issues affecting taxpayers across the State of California.

How is California dealing with the opioid crisis? Are there new initiatives being discussed or implemented? What is the role of pharmacists in what many are calling a public health emergency?

Stone: We have a statewide and national crisis over opioid addiction and overdoses. Fentanyl has burst onto the scene as a major killer of people who have become addicted to these dangerous drugs, and I am working with my colleagues on both sides of the political aisle to come up with a solution to stop the illicit importation of drugs like fentanyl.

One solution we are looking at involves improving the CURES database in California, to make it accessible to pharmacists on a real-time basis so pharmacists will know if patients are filling prescriptions at multiple locations. If we can bring this database into the 21st Century and make it accessible to physicians and pharmacists, we can save lives.

Drug prices, gag clauses, direct-to-consumer advertising, and pharmacy reimbursements have been thrust into the national debate. What role should pharmacists play as these discussion progress? How should we articulate the balance between price and innovation? How will this debate play out at the national level?

Stone: This is an issue that is particularly troubling to me as both a pharmacist and a state senator. The issue over gag clauses and reimbursement rates prompted me to successfully request a legislative audit of a local health system in California that has been slashing reimbursement rates to below acquisition costs to local independent pharmacies, presumably as a way to force patients to begin using the preferred PBM’s mail order services.

This issue was raised by a local pharmacist, and legislators and public policy leaders need to hear more from individual pharmacists to teach decision makers about the ramifications of so-called “cost cutting” measures that ultimately put patients at risk by reducing access to quality care.

California Governor Gavin Newsom’s first executive order directed the state’s health department to negotiate drug prices directly with pharmaceutical companies, and he took steps to enable states to manage a single-payer system. How would these initiatives affect pharmacists in the California? Do these changes have the potential to deliver on their intent?

Stone: I am looking closely at the governor’s order, but I am greatly concerned that having the state involved in drug price negotiations will severely reduce patient access to quality pharmacy services. Having the state in charge of purchasing drugs directly poses many challenges to physicians, pharmacists, and patients by potentially limiting the availability of necessary medications in many special circumstances.

Also, having the State of California function as a “super PBM” would likely force hundreds of pharmacies to close because it will certainly result in a rapid growth of mail-order pharmacy services, which might be fine in many circumstances, but these services do not necessarily work for patients needing specialized individual care and treatment.
DIVERSIFY & PROSPER

How to build new revenue streams and show your value by expanding services

By Beth Longware Duff, contributing writer

Independent community pharmacists might be the quick-change artists of the 21st Century, both out of necessity and by choice. Nimble enough to reinvent their practices in response to new economic and business challenges, they are increasingly adding innovative services that meet the dual purpose of delivering exceptional customer service and opening up additional and much-needed revenue streams. “Simply filling prescriptions as fast as possible is no longer a viable business model for most community-based pharmacies,” notes the 2018 NCPA Digest. “Strong local relationships and a focus on local healthcare service delivery is the backbone—and the future—of community pharmacy in America.”

Role Transformation

Long considered to be among the most readily accessible healthcare providers in the United States, community
pharmacists have always prided themselves on providing the highest quality of patient care. They just haven’t always been recognized or paid for their efforts. Those days are over, according to industry observers.

“The Expanding Role of Pharmacists in a Transformed Health Care System,” a paper issued by the National Governors Association (NGA) in 2015, notes the ongoing and significant transformation of the healthcare system in terms of both finances and delivery of services. It also recognizes the changing role pharmacists play by providing a wide variety of patient-centric services as part of an integrated healthcare team.

“Integrating pharmacists, who represent the third-largest health profession, into such systems is important for achieving intended goals,” the NGA states. “Pharmacists have the professional expertise to address key challenges facing the healthcare system, including the prevalence of people who have multiple chronic conditions and the increased use of more complex medications to manage those diseases.”

This new way of thinking coincides with today’s economic reality that independent pharmacists can no longer rely solely on prescription drug sales for their livelihood.

The Marketplace
In 2017, independent community pharmacy was a $77.6-billion marketplace, with 92% of sales derived from prescription drugs. However, gross margins as a percentage of sales decreased for the fourth straight year to 21.8%. NCPA attributes most of the reduction to below-cost reimbursement and unpredictable DIR fees in Medicare Part D.

Reimbursement has long been a thorn in the side of many community pharmacists trying to do business in a healthcare system where payment policies are driven by product-based reimbursement rather than the direct-care services provided to patients. For

So, you’re ready to expand your pharmacy’s offerings and add some patient services. Where do you begin?

Kurt Proctor, PhD, RPh, senior vice president of strategic initiatives at NCPA, notes that while there are a lot of different ways to diversify, not every option is right for every pharmacy.

“It’s important for pharmacists to make sure they’re remaining relevant to where healthcare is going,” he says. “It’s not just about the economics of dispensing, but it’s also that the payer community overall is changing. So they need to make sure they’re doing the things the marketplace is valuing.”

The 2018 NCPA Digest offers insight into the many steps independent community pharmacists are taking to help define the future of pharmacy practice and improve their return on investment.

The top three patient care services offered by pharmacies are medication therapy management (79%), compounding (60%), and durable medical goods (53%).

The No. 1 disease state management service is immunizations, offered by 70% of pharmacies. Blood pressure monitoring (57%), diabetes training (35%), smoking cessation (24%), and asthma management (16%) round out the top five services in this category.

Eighty-eight percent of pharmacies have deployed a comprehensive medication adherence program, with 93% reporting that they synchronize all meds to a single monthly pick-up date.

Seventy-one percent of pharmacies offer delivery services—most within six hours—and three-quarters of them do it for free.

Forty-five percent of pharmacists provide long-term care services to their patients, including seniors in skilled nursing and assisted living facilities, hospice, and home-based care. Specialty services range from nutrition assessment and support to intravenous therapy, durable medical equipment, ostomy, and pain management.

Forty-four percent of pharmacies dispense specialty medications, including rheumatoid arthritis (87%), HIV (58%), and MS (46%) meds.

Proctor, who is also president of the NCPA Innovation Center, says diversification has become an important part of the organization’s education program. Pharmacists who are interested in learning more can access the Diversified Revenue Opportunities section of the NCPA website for more information and inspiration.
example, one study reveals that while 80% of the respondents were providing medication therapy management (MTM) services directly to patients, only 35% were compensated for their efforts.

“The change in reimbursement structure is essentially placing a squeeze on the pharmacist’s ability to provide services in conjunction with prescriptions,” says Trista Pfeiffenberger, PharmD, MS, director of quality and operations at CPESN USA. Still, she says the organization’s members don’t want to compromise on the services they provide because they strive to give their patients the best care possible.

“We’re now at a point in healthcare where the movement to the value-based aspect on the medical side will really create a nice opportunity for pharmacies to see their business model flourish around services,” she says.

Phil LaFoy, RPh, is a co-owner of Blount Discount Pharmacy in Maryville, TN. Deeply invested in diversification at

FIVE TIPS FOR GETTING STARTED WITH NICHE SERVICES

As independent community pharmacists come to grips with the need to expand their services, pioneers of change who spoke with Drug Topics have some words of advice.

“If you’re trying to go toe to toe with fast, accurate, and cheap, it’s a losing battle.”

Jake Olson of Skywalk Pharmacy in Milwaukee says dealing with competition from chain and mail-order pharmacies reminds him of the “make hay while the sun shines” philosophy that prevailed on the farm where he grew up. “When it starts raining and the big boys decide to come after something that you’ve been doing for a while, go do something else!” he advises. “Either you’ve established yourself and you’ve done it really well, or you’re going to have to try to find something else. If you think you’re going to beat out the larger chains at their game, you’ve already gotten a big head start on you.”

“Engage with other pharmacists so you’re not in your own bubble.”

Stephanie Smith Cooney at Gatti Pharmacy in Pennsylvania promotes a sharing approach. “Statewide and nationwide there’s a lot of innovation happening, and independent owners as a group are generous, interested, and willing to share their ideas,” she explains. “We’re stronger together when we can share our ideas, and don’t just hole up and do our own thing. Being involved is a good way to get new ideas and to have people to serve as resources when you’re trying to vet a new idea.”

“Read and see all the new things that the chains are going to roll out.”

Phil LaFoy from Blount Discount Pharmacy in Tennessee takes a cue from emerging trends, which he says he can act on more quickly than big corporations. “I don’t have to go up the corporate ladder to make a decision. I call my partner and say, ‘What do you think about this?’” he says. “We’re all about willingness to change. The people who don’t adjust and change are going to dry up on the vine.”

“If we don’t document what we do, we’ll never be paid for what we do.”

Kurt Proctor, senior vice president of strategic initiatives at NCPA, notes that documentation is the way the rest of healthcare works. “It’s not rocket science,” he points out. “Those pharmacies that have adopted some form of a clinical documentation system are finding, first and foremost, that it helps in the store operationally.”

“Pharmacies think they can wait, and they really can’t.”

Trista Pfeiffenberger of CPESN urges pharmacists to act now to stay relevant and financially sustainable in their communities. “When health plans need a solution, they need a group that’s ready to go,” she warns. “That means you need to be striving to make these changes in your practice to be ready for these opportunities every day. Consider your options to get to the place where you’re ready for the Healthcare 2.0 that’s coming.”

About 15 years ago, we decided pediatrics was a category that other pharmacies and chains really weren’t focusing on. JAKE OLSON, PHARMD
his three retail outlets, he offers a variety of services including immunizations, hospice care, compounding services, a diabetes care program, smoking cessation classes, MTM, and a medication compliance program.

LaFoy likens the core of his business to the hub and spokes of a wheel. “The hub is our long-time loyal customers, patients, and family members who come to us generation after generation. The spokes are our services,” he explains. Diversification, he adds, “ultimately grows the business, but primarily it helps us take better care of people we have.”

**Niche Services**
Jake Olson, PharmD, made the decision several years ago to add niche services to his pharmacy. Choosing which services to offer was practically a no-brainer and was based primarily on one factor—location, he says.

Olson’s Skywalk Pharmacy is situated at Children’s Hospital in Milwaukee. “About 15 years ago, we decided pediatrics was a category that other pharmacies and chains really weren’t focusing on,” he explains. Within that niche, Olson concentrates on providing services for kids who are undergoing treatment for brain tumors, recipients of a heart or solid-organ transplants, and growth hormone patients.

The primary focus is on transitioning these young patients smoothly from hospital to home, which is often located in a small rural town where the local pharmacy may have limited experience in treating such complicated medical conditions.

Olson’s solution was to establish a med sync program. “When you have a kid on 10 different medications—some of them are compounded, some are specialty and not available at all pharmacies—you’re proactively working with the mother, the doctor, and the insurance company for prior authorizations to make sure you don’t have a gap in therapy,” he says. “A gap in therapy for a guy with cholesterol or Type II diabetes medication is troublesome, but when you have a kid with a heart transplant, there cannot be a gap.”

**Meeting Community Needs**
At Gatti Pharmacy in the college town of Indiana, PA, owner Stephanie Smith Cooney, PharmD, tailors her offerings to the specific needs of the community. In addition to discounts, prescription transfers, free delivery, and the Rx Local App aimed at students, she lists immunizations; travel medicine consultations; diabetes prevention; special packaging; med sync, comprehensive medication reviews; and mastectomy, bracing and diabetic shoe fittings as good returns on her investment.

“For many of the services that we provide, we just see an opportunity, and we try it and see if it works. If it does, we continue to offer it. If not, it doesn’t last long,” she says. “A big part of a new service consideration is whether or not it checks the boxes of potentially helping us move more into the clinical world and providing value to the patient and the provider.”

LaFoy says he has some winning services (immunizations, travel medicine, diabetes education) and at least one—specialty pharmacy—that worked for a while, but eventually faded and was sold. And then there’s MTM.

“I’m not making any money on MTM, but I’m not losing any money,” he admits, adding that he can’t afford not to do it. “With all the Star Ratings and compliance numbers, we decided to hire a really good pharmacist to take care of this because it’s a lot of work. He gets more phone calls than I do. He’s out in the community and has become one of the faces of the company because he touches so many lives.”

**The “M” Word**
Marketing, as defined by the American Marketing Association, is the process for “creating, communicating, delivering, and exchanging offerings that have value for customers, clients, partners, and society at large.” It sounds simple enough, but not everyone is comfortable tooting their own horn, says Kurt Proctor, PhD, RPh, senior vice president of strategic initiatives at NCPA.

“Clearly, being able to market yourself might have sort of a retail sound to it, but it’s really a skill that everybody needs to have,” he says. “Whether you’re promoting yourself internally to upper management in a health system or talking to payers or to consumers, you do need to know how to promote yourself and talk about the value of what you’re bringing.”

Marketing is a concept that Liz Tiefenthaler, president of Pharm Fresh, advises pharmacists on to help them get over their aversion to self-promotion. “I like to tell people they’re not building a field of dreams. Just because it’s there doesn’t mean people are going to show up,” she explains.

Tiefenthaler says the marketing challenge is to reach people who are so bombarded with information that they’re effectively on autopilot. She tells pharmacists that the key to breaking through
that fog and reaching potential customers is to become their habit.

“We used to feel like we could reach a new customer in about five touches, but now it’s up to 19 because they are just so deluged all day long with information,” she explains. “That means you’re going to have to try a lot of different things. It’s not just one platform.”

Marketing is also a significant chunk of the Enhanced Services Boot Camp run by CPESN USA and NCPA, says Jay Williams, CPESN’s Director of Marketing Communications. He maintains that the notion of consumer choice often goes by the wayside in the healthcare system.

“You have insurance, and the insurer is directing the patients to where they can and can’t go, and doing so with incentives to go to this place versus that place,” observes Williams. “You can get a lot of new customers into your pharmacy, but if the insurance is unwilling to work with you or reimburse at the same rates, it makes it more challenging.”

**Taking on the Competition**

Katherine O’Neal, PharmD, MBA, agrees that it’s extremely important that independent pharmacists market themselves, especially in light of competition from chain and mail-order pharmacies. O’Neal is associate professor at the University of Oklahoma College of Pharmacy. “I don’t think independent pharmacies can compete at the same marketing or advertising budget that the large retail chain stores have, so what they do at the community level with their customer loyalty and the services they provide is key to success,” she says.

Cooney admits that she personally isn’t comfortable with marketing, but she recognizes its importance to her business. She has had a part-time marketing professional on staff for the last five years to promote all the different ways the pharmacy takes care of its patients.

“We spend a lot of time working on our website, making sure it’s changing and relevant and doing some things with key words so people can find us if they’re looking for specific services,” she says. The pharmacy also has a social media presence, a newsletter, and an email program to get the message out to established and potential customers.

Olson establishes his pharmacy’s reputation by going above and beyond the expectations of his patients and providing services they can’t get at other pharmacies. “You want the people who are affected by whatever disease state you are an expert in to say, “This is the place you go,” he says.

**Pharmacists Helping Pharmacists**

The current challenge facing all medical providers—pharmacists especially—is the ongoing transformation of the U.S. healthcare system to a value-based care and reimbursement model. Pharmacists are adapting to this new reality in the ways outlined above as well as by adopting a concept already in use in other areas of healthcare: a clinically integrated network of community pharmacies

CPESN USA is a shared services entity for dozens of localized CPESN networks. Member pharmacists collaborate to improve the quality of care offered to patients and to offer value to payers through enhanced services and lower costs. In return, they receive a share of the money that payers save in patient care costs as a result of the services they provide. CPESN USA has two non-profit member owners, Community Care of North Carolina and the NCPA, and it is managed by representatives from the local networks.

"Routine patients just need a pharmacy to get their prescription filled. More complex patients—the ones costing the system money, who are difficult to reach, who have difficulty understanding what’s going on with them—are the ones CPESN is primarily focused on and delivering the enhanced level of care they need to lower their total healthcare costs," NCPA’s Proctor explains.

Williams at CPESN acknowledges that the concept of spending money to make money can be a tough sell for pharmacists who’ve had their hopes for reimbursement raised and dashed many times in the past. However, he advises that the time to act is now.

“The payer community is going to come around and start to reimburse for these services, so pharmacists have to jump on this opportunity to provide those services and to tell their story differently before they fall to the same fate of independent community pharmacies that have closed over the years,” he says. Even a big box chain like Target decided to get out of the pharmacy business by selling its in-store pharmacies to CVS, he notes.

Beth Longware Duff has been a medical and healthcare writer for several years. She lives in the Finger Lakes region of New York.
IMPORTANT SAFETY INFORMATION AND INDICATIONS

Indications
FIRVANQ™ (vancomycin hydrochloride) is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of:

- *Clostridium difficile*-associated diarrhea
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

Contraindications
FIRVANQ™ is contraindicated in patients with known hypersensitivity to vancomycin.

Important Limitations of Use
- Parenteral administration of vancomycin is not effective for the above infections; therefore, vancomycin must be given orally for these infections.
- Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections. To reduce the development of drug-resistant bacteria and maintain the effectiveness of FIRVANQ™ and other antibacterial drugs, FIRVANQ™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Warnings and Precautions
- FIRVANQ™ must be given orally for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.
- Significant systemic absorption has been reported in some patients (e.g., patients with renal insufficiency and/or colitis) who have taken multiple oral doses of vancomycin hydrochloride for *C. difficile*-associated diarrhea. Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. Monitoring of serum concentrations of vancomycin may be appropriate in some instances, e.g., in patients with renal insufficiency and/or colitis or in those receiving concomitant therapy with an aminoglycoside antibacterial drug.
- Nephrotoxicity has occurred following oral vancomycin hydrochloride therapy and can occur either during or after completion of therapy. The risk is increased in geriatric patients. In patients over 65 years of age, including those with normal renal function prior to treatment, renal function should be monitored during and following treatment with FIRVANQ™ to detect potential vancomycin induced nephrotoxicity.
- Ototoxicity has occurred in patients receiving vancomycin. It may be transient or permanent. It has been reported mostly in patients who have been...
given high intravenous doses, who have an underlying hearing loss, or who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside. Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.

- Use of FIRVANQ™ may result in the overgrowth of non-susceptible bacteria. If superinfection occurs during therapy, appropriate measures should be taken.
- Prescribing FIRVANQ™ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.
- Hemorrhagic occlusive retinal vasculitis, including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by the intracameral or intravitreal route have not been established by adequate and well-controlled studies. Vancomycin is not indicated for prophylaxis of endophthalmitis.

Adverse Reactions
- The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%) and hypokalemia (13%).

To report SUSPECTED ADVERSE REACTIONS, contact CutisPharma, Inc. at 1-800-461-7449, EXT 103; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use FIRVANQ™ safely and effectively. See Brief Summary of Full Prescribing Information for FIRVANQ™ on the next page.

FIRVANQ™ (vancomycin hydrochloride) is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of:

- *Clostridium difficile-associated diarrhea*
- *Enterocolitis caused by Staphylococcus aureus* (including methicillin-resistant strains)

**Important Limitations of Use:**
- Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of FIRVANQ™ and other antibacterial drugs, FIRVANQ™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

**INDICATIONS AND USE**

FIRVANQ™ is also indicated to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. It should only be used in patients when bacterial infection has been clearly demonstrated or strongly suspected. It is not indicated for prophylaxis of endophthalmitis.

**WARNINGS AND PRECAUTIONS**

- **FIRVANQ™ must be given orally for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis.** Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections. Parenteral administration of vancomycin is not effective for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. If parenteral vancomycin therapy is desired, use an intravenous preparation of vancomycin and consult the package insert accompanying that preparation.
- **Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of vancomycin hydrochloride for *C. difficile*-associated diarrhea.** Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. These patients may be at risk for the development of adverse reactions associated with higher doses of FIRVANQ™; therefore, monitoring of serum concentrations of vancomycin may be appropriate in some instances, e.g., in patients with renal insufficiency and/or colitis or in those receiving concomitant therapy with an aminoglycoside antibacterial drug.
- **Nephrotoxicity has occurred following oral vancomycin hydrochloride therapy and can occur either during or after completion of therapy.** The risk is increased in geriatric patients. Monitor renal function.
- **Hypersensitivity to vancomycin**

**Pregnancy**

There are no available data on FIRVANQ™ use in pregnant women to inform a drug-associated risk of major birth defects or miscarriage.

**Lactation**

There are insufficient data to inform the levels of vancomycin in human milk.

**ADVERSE REACTIONS**

The most common adverse reactions (≥10%) were nausea (17%), abdominal pain (15%) and hypokalemia (13%).

**Table 1: Common (≥5%) Adverse Reactions* for Vancomycin Hydrochloride Reported in Clinical in Clinical Trials for Treatment of *C. difficile*-Associated Diarhea**

<table>
<thead>
<tr>
<th>System/Organ Class</th>
<th>Adverse Reaction</th>
<th>Vancomycin Hydrochloride (%) (N=260)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Diarrhea</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Flatulence</td>
<td>8</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Edema peripheral</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
<td>5</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Urinary tract infection</td>
<td>8</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Hypokalemia</td>
<td>13</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Back pain</td>
<td>6</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>7</td>
</tr>
</tbody>
</table>

* Adverse reaction rates were derived from the incidence of treatment-emergent adverse events.

**USE IN SPECIFIC POPULATIONS**

**Geriatrics:** In patients over 65 years of age, including those with normal renal function prior to treatment, renal function should be monitored during and following treatment with vancomycin hydrochloride to detect potential vancomycin induced nephrotoxicity. Patients over 65 years of age may take longer to respond to therapy compared to patients 65 years of age and younger.

**Pregnant women:** There are no available data on FIRVANQ™ use in pregnant women to inform a drug-associated risk of major birth defects or miscarriage.

**Nursing mothers:** There are insufficient data to inform the levels of vancomycin in human milk.

**OVERDOSAGE**

Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance.

**PATIENT COUNSELING INFORMATION**

**Antibacterial Resistance:**

Patients should be counseled that antibacterial drugs including FIRVANQ™ should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When FIRVANQ™ is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by FIRVANQ™ or other antibacterial drugs in the future.

**Important Administration Instructions:**

Instruct the patient or caregiver to:
- Shake the reconstituted solutions of FIRVANQ™ well before each use and to use an oral dosing device that measures the appropriate volume of the oral solution in milliliters.
- Store the reconstituted solutions of FIRVANQ™ at room temperature, do not refrigerate.

**To report SUSPECTED ADVERSE REACTIONS, contact CutisPharma, Inc. at 1-800-461-7449, EXT 103;** or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**Initial U.S. Approval:** 1964

Manufactured for Cutis Pharma

941 Woburn St, Wilminton, MA 01887 USA

Rev. 2/2018
Nine Ways to Help Patients Better Adhere to Their Medications

When a nonadherent patient was admitted to the emergency department several times a month for several months, Kim Tran, PharmD, a pharmacist at the Community-University Health Care Center at University of Minnesota in Minneapolis, started meeting with him once a week. “During the first meeting, I introduced myself and my role on the care team and established goals with the patient,” she says. “Then we moved on to troubleshoot why he wasn’t meeting his health goals.”

The patient shared that he was a chronic alcohol user who also had a seizure disorder. When he drank, he would pass out and not take his anti-seizure medications, which then led to having seizures that sent him to the emergency department, Tran recalls.

“We explored several ways that he could remain on his antiseizure medications even if he was not ready to stop drinking,” Tran says. “He first kept his medications in bottles by his bedside to try and remember, but found it difficult to recollect if he took the dose that day or not. Then, we tried placing weekly medications in a medication box, with each day written on it so the patient could tell if he took medication that day. By doing this and continuing weekly check-ins, the patient was in the driver’s seat of managing his own health. He was allowed to set his own goals and empower himself. This eventually led to decreased emergency department use because his seizures disappeared when he took his medications daily.”

A study in the journal Social Health estimated that poor medication adherence in the United States leads to $100 billion in healthcare expenditures annually. Because of the variety of services pharmacists provide, they have unique opportunities to work closely with patients to help them understand barriers to medication adherence and develop individualized plans that address those barriers, says Batoul Senhaji-Tomza, PharmD, MPH, assistant dean of curriculum and associate professor at Touro College of Pharmacy in New York. Here are nine methods to help nonadherent patients.

1. Assess why the patient is nonadherent.

“Before you can begin to help someone, you need to get to the root cause of why they stopped taking or are not taking their medications properly,” says Fernando Gonzalez, RPh, MS, assistant professor of pharmaceutical sciences at Long Island University Arnold and Marie Schwartz College of Pharmacy in Brooklyn.

According to a survey conducted by Express Scripts in collaboration with...
Russell Research, more than two-thirds of medication nonadherence is behavior-driven; it’s either caused by forgetfulness or procrastination. “Respondents stated that they didn’t want human intervention to correct these harmful behaviors and rated family members as the least effective source of medication reminders,” says Kyle Amelung, PharmD, BCPS, senior manager of clinical solutions at Express Scripts. “However, technology-based medication reminders are well-received, especially among adults under age 55.”

Other common reasons why a patient may be nonadherent are busy schedules, substance abuse, depression, misconceptions about potential adverse effects or therapy outcomes, high cost, having a complex medication regimen, and low literacy, says Senhaji-Tomza.

When conducting medication adherence assessments, pharmacists can address barriers by guiding patients by asking open-ended questions. For example, pharmacists can adopt a variation of the Morisky Medication Adherence Scale (MMAS). “The MMAS scale uses an eight-point scale of open-ended questions geared toward measuring specific medication-taking behaviors and attitudes,” Senhaji-Tomza says.

2. Review a patient’s medication plan with them.

When meeting with a patient, Tran says pharmacists should discuss each medication individually and highlight the reason for taking the medication, how it will help achieve health goals, possible side effects, and how the patient can obtain it and take it safely. The pharmacist should assess all of a patient’s current medications and how they interact, taking into consideration the patient’s individual lifestyle and health conditions. By doing a review, pharmacists may be able to find out if a patient isn’t adherent and why.

3. Provide enhanced patient counseling.

Counseling considers a patient’s lifestyle and diet based on region and culture. “These factors can have varying effects on the way a medication may behave in someone’s body,” Tran says.

Sarah A. Boswell, PharmD, a clinical pharmacist at Cherokee Health Systems in Knoxville, TN, is a proponent of using the teach-back method during counseling to determine if a patient comprehends the information she provides by having the patient summarize it. “If a patient understands their drug therapy and buys into it, they are much more likely to adhere,” she says.

4. Establish trust.

A pharmacist can establish trust by answering the patient’s questions, being an attentive listener, and showing empathy to their concerns and feelings. “The patient will see you as a resource to help them improve their health and be more motivated to be accountable,” Boswell says.

Following up with patients helps ensure they’re meeting goals and that side effects and concerns are quickly addressed. “Through frequent followups, trust is formed and relationships are built,” Tran says. “Once patients trust a pharmacist and they start meeting their health goals, they are more likely to continue with the current therapy.”

5. Communicate effectively.

Effective communication is born out of effective listening. “It can be tempting to only provide information; however, starting with open-ended questions enables a pharmacist to learn more about a patient’s specific difficulties and tailor any counseling to that specific situation,” says Clark Kebodeaux, PharmD, BCACP, clinical assistant professor at the University of Kentucky College of Pharmacy.

We explored several ways that he could remain on his antiseizure medications even if he was not ready to stop drinking.

KIM TRAN, PHARMD

<table>
<thead>
<tr>
<th>U.S. MEDICATION ADHERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 BILLION</td>
</tr>
<tr>
<td>Prescriptions filled annually</td>
</tr>
<tr>
<td>50% Taken Incorrectly</td>
</tr>
<tr>
<td>$300 BILLION</td>
</tr>
<tr>
<td>Direct healthcare costs of nonadherence</td>
</tr>
<tr>
<td>125,000 Deaths from nonadherence</td>
</tr>
</tbody>
</table>

Source: 2017 data from Kaiser Foundation, NIH, NACDS
Pharmacy in Lexington, Kentucky.

Tran emphasizes that pharmacists use accessible and respectful language to help patients understand health issues and how medications and lifestyles contribute to and treat each disease state. “When needed, we use interpreters who are more familiar with a patient’s individual culture and are able to help pharmacists understand more about a patient’s lifestyle, such as meal choices,” she says.

6. **Help patients set goals.**

Tran says she sets all goals together, such as laboratory goals (such as A1c or blood pressure) and the patient’s personal goals (such as running a mile or playing with grandchildren). As laboratory goals start to improve, patients may feel physically better. “With each encounter, we revisit goals and assess whether or not the patient has achieved them. If not, the care team assesses how to adjust the goal and make it more achievable,” she says.

7. **Take advantage of technology.**

Many consumers are tech savvy and embrace opportunities to use technology. Express Scripts, for example, has capitalized on mobile health applications that allow patients to review medication lists, set reminders, and receive clinical messaging and coaching sessions from certified healthcare professionals. "Patients can even add over-the-counter medications and herbal or dietary supplements to their profile, allowing medication interactions to be flagged based on their complete medication list," Amelung says. "These tools are also leveraged during physician and pharmacy visits, which leads to better health discussions and decisions at the point of care."

To promote clinical engagement and greater adherence, Express Scripts offers a game-like approach to medication management. “Through a mobile application, patients can accumulate points and earn rewards by logging health data and achieving medication goals,” Amelung says. “Our data show that improved clinical engagement equates to better care experiences, better health outcomes, and lower costs year-over-year.”

8. **Help patients save money.**

One way to help patients save money is for pharmacists to help Medicare Part D patients choose the best plan for them during the open enrollment period, Gonzalez says.

“A pharmacist can input the patient’s prescription needs as well as other important healthcare information, such as deductibles, copayments, and mail order options to help them choose the plan that would save them the most money,” he says.

9. **Employ existing programs.**

Several nationally sponsored programs are available to support pharmacists in reinforcing medication adherence, Senhaji-Tomza says. For example, Simplify My Meds is a free service available through the NCPA. “The program helps pharmacists consolidate and coordinate all of a patient’s prescription pickups on the same day every month,” she says. “Participation saves patients multiple trips to the pharmacy while streamlining pharmacy operations, therefore freeing time for pharmacists to engage in more meaningful patient interactions.”

**DrugTopics | FEBRUARY 2019 | DRUGTOPICS.COM**
"I love the way Liberty developed a workflow queue system so we can find where a prescription is in the process.”

**JIM HRNCIR**, Owner, Pharmacist, Las Colinas Pharmacy

“What I really like about them is if we have something that isn’t working for us, we can call them and say what can you guys do to help us do it better.”

**STACHIA BAXTER**, Pharmacy Manager, Roanoke Pharmacy

“The system is user friendly and because every pharmacy is different, they will customize it to your needs.”

**JUDY HARRIS**, Owner, Pharmacist, All-Care Pharmacy
Independent Pharmacies, Chains Enter Specialty Space

Physician referrals, volume, niche services help hedge success

By Mari Edlin, contributing writer

If PBMs and payers can succeed in the specialty pharmacy arena, why shouldn’t community pharmacies get into the act?

Forty-four percent of independent community pharmacies dispense specialty medications, with treatments for rheumatoid arthritis (87%), HIV (58%), and multiple sclerosis (46%) topping the list of disease states, according to the 2018 NCPA Digest. By 2021, 50% of drug spend is expected to be specialty drugs; however, these drugs make up only 2.5% of all drugs, according to IQVIA.

There is a good chance that chains and independent pharmacies will provide specialty medications if they have patients that regularly use their pharmacy and if they can acquire the drug from their wholesaler, says William Sullivan, principal consultant and general manager, Specialty Pharmacy Solutions LLC in Orlando.

"It is less likely when the specialty drugs are very expensive, and independents may not want to bear the cost of inventory, wait to get reimbursed, or lack the time and resources to navigate time-consuming efforts to obtain prior authorizations," he says. "Therapeutic categories that don’t require significant patient monitoring, such as HIV, are more common with independents."

Suzette DiMascio, president/CEO of CSI Specialty Group, a consulting firm in Sanford, Florida, says if she were an independent pharmacy today, she would not venture into the specialty arena. PBMs are locking out small pharmacies to steer customers to their own specialty pharmacies, she says. "They want to get their feet wet while the specialty pipeline is rich, but they don’t have the economies of scale that chains do," she says. "Independents might start off winning the specialty war because of their close relationship with prescribers, but physicians are often forced to work with PBMs."

The only way DiMascio feels independents have a chance to succeed is if they develop a contract with a health system or create a niche, such as medications for children’s diseases.

A High-Touch Approach

Although independent community pharmacies are relatively new to specialty medications, John Becker, RPh, senior director of strategic initiatives for NCPA, believes they should be able to deliver these medications even if they are not full-fledged specialty pharmacies. "If they are dispensing traditional drugs to their customers, they should be allowed to also deliver specialty—as long as they are accredited to do so," he says.

Drug Channels reports that, in 2017, independents made up more than half of the 729 unique pharmacy locations that earned accreditation from two or three of the accreditation organizations. DiMascio says that accreditation—a time-consuming process with many requirements—is no longer optional. Some PBMs are pressuring independent pharmacies to acquire accreditation within 18 months, making it almost prohibitive to get into the specialty business, she notes.

"Patients trust their independent community pharmacist with all of their healthcare needs, including specialty medications," Becker says. "These medications often require additional counseling and other high-touch services due to their complex regimens, making the relationship with a community pharmacist all the more important."

Gerry Crocker, CEO of the Association of Affiliated Pharmacies and Apothecaries (AAPA) in Detroit, a pharmacy buying group, agrees with Becker that patients like doing business with independents, where they can receive counseling. "Mail order doesn’t generate the same adherence as going to a pharmacy, and when compliance of 90% or more is necessary for HIV drugs—the largest specialty seller—compliance is important," he says.

The majority of specialty drugs are in the limited distribution drug category, where manufacturers decide which qualified specialty pharmacies gain access to their drugs. HIV and hepatitis C drugs are not limited and are available through general distribution channels, Crocker says.

The downside is that HIV and hepatitis C drugs require clinical care services 24/7. With that additional overhead plus low reimbursement and high costs for these drugs, Crocker says he has witnessed pharmacies go under water on every script.

However, Sullivan says it is possible to be profitable, depending on the class of drugs, acquisition costs, and payer mix that can dictate reimbursement.
Although he is seeing more independents jump into specialty pharmacy because they believe they can increase profitability, he says they have been losing business to big PBMs for specialty pharmacy for years.

Crocker points out that some payers are reclassifying drugs as specialty drugs, which allows them to be more aggressive on reimbursement rates.

**Chains and Specialty Pharmacy**

"More chains are joining the specialty pharmacy space and need to know how to play in it and how to help patients," says Chris Creamer, BSPharm, senior director of special pharmacy operations for Walgreens.

The chain has more than 300 community-based pharmacies dedicated to specialty medications, including access to limited distribution drugs, and complex high-touch patient care services with trained staff. Its pharmacists work to coordinate care and prior authorizations. Creamer estimates that Walgreens’ community pharmacies dispense 80 limited-distribution medications.

Even if specialty drugs are delivered by mail order, patients may receive consultation by phone or face to face. "There is connected service no matter where a consumer receives a drug. We emphasize expedited triage," he says.

Walgreens tailors sites based on a preponderance of certain conditions in particular locations, Creamer says. For example, if a hospital has a transplant program, trained pharmacists for transplant surgery will staff a nearby Walgreens pharmacy.

Kroger Prescription Plans offers a model that encompasses traditional retail in its grocery stores, specialty pharmacies, and what Richard Adams, senior vice president of Kroger Prescription Plans, describes as "a specialty-at-retail-program." These are Kroger community pharmacies that dispense traditional and some specialty drugs, but also provide nutritional, wellness, and community education services.

The majority of specialty drugs dispensed in retail tend to be drugs that can be self-injected or taken orally, such as those for rheumatoid arthritis, HIV, and transplants. In many instances these conditions require special patient counseling because of their potential side effects, while other classes do not need special storage or counseling. Asthma, migraine, and oncology drugs—if they can be self-administered—also can be dispensed in the retail environment.

**Independents have a chance to succeed only if they develop a contract with a health system or create a niche, such as medications for children.**

Adams says the investment in specialty drugs can be "wildly" expensive, and can include building receiving facilities, special storage and handling, utilization management, efficient delivery, and a place to administer drugs, all of which require extra space. Pharmacies that dispense some specialty drugs also need to be accredited, licensed, and have trained pharmacists and staff.

The Kroger model generates greater adherence and health outcomes because its community-based pharmacists can engage with customers and patients in positive ways, helping them optimize health outcomes through wellness, disease management, and medication therapy management services, he says.

**Is It Worth the Effort?**

Becker admits there are challenges for independents venturing into the specialty drug market. "It’s a daily battle for them to compete, but the easiest way is through physician referrals," he says. "Competition is the name of the game. Pharmacies want to keep patients or else they may go elsewhere." Entering the specialty marketplace also takes efficiency, prior authorization knowledge, and copayment reduction programs, he adds.

"Community pharmacists also require a steady stream of users to be profitable as they invest in specialty drugs from wholesalers to put on their shelves. Finally, reimbursement for specialty is often ratcheted down by PBMs," Becker says.

Sullivan adds one more caveat: Pharmacies usually segregate specialty from retail operations to minimize operational disruptions and support a patient-centric service model that is not part of the retail model. "If they want to get out of retail, they need to find new ways to do so," Crocker says. "They are nipping at the heels of chain pharmacies from a pricing/access standpoint." Purchasing groups like AAPA can help because they allow smaller pharmacies to buy drugs collectively with a prime vendor agreement.

Crocker acknowledges that the specialty drug marketplace might not be for the faint of heart, pointing out necessary investment in data reporting, buying and tracking inventory, high costs and low margins, call centers, accreditation, and inventory. In order to dispense a wide variety of specialty, it could cost as much as $500,000, he says.

But, independents can compete if they develop relationships with specialty prescribers; provide services to providers, such as help with prior authorization; and partner with payers for inclusion in their specialty networks, he says.

Mari Edlin is a medical writer based in California and a contributor to Drug Topics for more than 20 years.
Pain management is a struggle when pharmacists and prescribers are faced with drug shortages, says Shannon Manzi, PharmD, BCPPS, director of clinical pharmacogenomics services in the Division of Genetics and Genomics at Boston Children's Hospital.

For example, she points to a situation where she and the pharmacists on her team had to map out the provision of opioid-based pain medications for surgical patients. Three of the options they had that were in short supply were hydromorphone, sufentanil, and fentanyl, based on each drug’s availability.

During the drug shortages, Manzi’s team collaborated with stakeholders from ICU units, anesthesia, the pain service, and operating room staff to determine which patients got hydromorphone, sufentanil, and fentanyl, based on each drug’s availability.

While these drug shortages are no longer an issue, Manzi learned some lessons she applies to current shortages. Those lessons also informed the tough questions she tackles regarding shortages.

These questions include:
- How much of this medication do we have on hand?
- How can we obtain more?
- How do we get it to the appropriate patients?
- How do we log it in the electronic health record (EHR) so it’s not orderable?
- How do we guide clinicians in the EHR to alternate medications and how to prescribe them?

Operating Mechanisms

Unforeseen events happen. That was the case after Hurricane Maria in September 2017, when access to medications, such as injectable opioids and certain IV fluids, were in short supply.

In response, Boston Children’s Hospital’s emergency management team organized the various stakeholders for weekly meetings to discuss the drugs currently on hand, the patients who could use other interventions, and strategies for minimizing nonessential use of those drugs in short supply, Manzi says. Some of these interventions included coordinating pharmacy-prepared IV fluids, encouraging enteral (oral use, sublingual use, or rectal administration) over parenteral (intramuscular, subcutaneous, or intravenous) medications, and...
and changing delivery from IV bags to syringes where possible.

Still, making changes under duress is not the best way to introduce medication alternatives to doctors and nurses. These changes—whether they’re about different concentrations or ways of mixing a medication or administration—require changes to prescriber behavior; they also involve orchestrating changes in prescriber order entry, barcode medication administration, and availability of syringes also dipped, since other hospitals around the country were doing the same thing.

As an alternative, nurses at Boston Medical Center used IV push antibiotics with patients where appropriate, says Vreeland. This required nurses to mix antibiotics with sterile water and inject it for five minutes into the patient’s IV line, she says. Then the nurse would flush the IV line.

This isn’t the way nurses usually administer antibiotics, which meant many needed training. But there was a “silver lining,” she says. Nurses appreciated that they were able to spend more time with patients.

During the worst of the two months of shortages caused by the hurricane, Vreeland’s team was in crisis mode every day. All told, managing the crisis from a drug-access perspective stretched about 10 months, starting shortly after the hurricane hit until the following August.

During the worst of the two months of shortages caused by the hurricane, Vreeland’s team was in crisis mode every day. All told, managing the crisis from a drug-access perspective stretched about 10 months, starting shortly after the hurricane hit until the following August.

Developing responses to shortages caused by Hurricane Maria was the most challenging pharmacy-related crisis Vreeland has worked on in 20 years, she says. Going forward, hospitals should be aware of the locations where drugs aren’t available. Since she often doesn’t know the reason, she provides them with general reasons that drugs can be in short supply.

She laments the lack of transparency by drug manufacturers regarding supply chain issues that lead to shortages. The FDA could mandate more transparency from drug companies, she says.

While her team receives projected availability dates for drugs that are in shortage, the timelines are very broad. For example, she may learn that a drug is projected to be available in Q2 next year. That broad timeline doesn’t give her the information she needs to plan around the drug shortage.

Manning works with the hospital’s pharmacy and therapeutics committee, which includes attending-level physicians across most specialties. It’s the physicians who determine the appropriate approaches for different patient populations when the hospital is faced with shortages.

The hospital develops a master list of drugs that are in shortage and makes it available to pharmacy staff and prescribers, says Manning. New drug shortages, restrictions, and status updates are sent by email each week to pharmacy staff, physicians on the pharmacy and therapeutics committee, and nursing leaders.

When a prescriber tries to order a restricted drug in the EHR, they’re alerted about the appropriate patient populations for the drug and alternatives for other patients. For example, if there’s a shortage of IV formulations, the oral formulation will be appropriate for many patients. The order is also verified by a pharmacist after the prescriber submits it, Manning says.

Manufacturer Transparency

Boston Medical Center’s Vreeland says doctors and nurses want to know why drugs aren’t available. Since she often doesn’t know the reason, she provides them with general reasons that drugs can be in short supply.

She laments the lack of transparency by drug manufacturers regarding supply chain issues that lead to shortages. The FDA could mandate more transparency from drug companies, she says.

While her team receives projected availability dates for drugs that are in shortage, the timelines are very broad. For example, she may learn that a drug is projected to be available in Q2 next year. That broad timeline doesn’t give her the information she needs to plan around the drug shortage.

Aine Cryts is a medical writer and regular contributor to Drug Topics.
Avoiding Pharmacist Burnout

Professional associations, gratitude can keep you engaged, healthy

By Keith Loria, contributing writer

A recent study in the *American Journal of Health-System Pharmacy* reported that more than half of health-system pharmacists have a high-degree of burnout. Healthcare experts say all involved in the pharmacy industry—including student pharmacists and pharmacy residents—are also at risk of burnout in their careers.

The study revealed that 53.2% of health-system pharmacists reported scores indicating a high degree of burnout on at least one subscale of the Maslach Burnout Inventory-Human Services Survey (MBI-HSS). This is similar to published burnout rates for physicians and nurses.¹

Shareen El-Ibiary, PharmD, BCPS, FCCP, professor and chair of the Department of Pharmacy Practice, Midwestern University College of Pharmacy-Glendale, was involved in a study that looked at burnout rates among pharmacy practice faculty. That study revealed that 41% were experiencing high levels of emotional exhaustion, one dimension of burnout.²

Additionally, a 2017 study among clinical pharmacists also showed high levels of emotional exhaustion (61%).³

“We found that many faculty work longer hours, and those that worked 50 hours or more per week had higher levels of emotional exhaustion,” she says. “We also found that women, junior faculty, those with young children (1 to 12 years old), those without a mentor, and those without a hobby had higher levels of emotional exhaustion.”

Why So Much Burnout?

Christina Martin, PharmD, director of membership forums with the ASHP, says burnout is associated with compromised patient safety and a loss of productivity in the workforce.

“Stress and burnout can be caused by individual factors, external factors, or a combination,” she says. “Individual factors can include personal factors, such as family dynamics, sense of purpose, or personal financial stressors.” External factors, which the research suggests carry more weight in contributing to burnout, can include maintenance of license and certification, increased rules and regulations, workload, high employee turnover, and drug shortages.

Erin Albert, PharmD, senior director for education for the American Society of Consultant Pharmacists, says some of the reasons for burnout in pharmacy are pressure to perform at better and faster rates, needing to do more with fewer resources and time, and increased competition in the workplace with more pharmacy schools producing more pharmacists.

“It’s not a new problem, but it’s a problem that has increased over time and accelerated due to increased competition, decreased margins on traditional prescription filling and metric constraints,” she says.

“We see it in all areas of practice too, even areas where there is a (false) perception that pharmacy jobs are ‘easier’ than retail or hospital, such as pharmacy academia,” she adds.

A systematic review on burnout across industries found that problems like cardiovascular diseases, pain, depression, job dissatisfaction and higher absenteeism in the workplace are all effects of burnout.⁴

“Burnout literally changes our brains,” Albert says. “That’s why it is so important for self-care with healthcare professionals.”

Maria Marzella Mantione, PharmD, CGP, FAPhA, an associate clinical professor at St. John’s University College of Pharmacy and Health Sciences in New York, says the problem is prevalent. “The list of responsibilities keep growing, but the resources, even with technology and all the efficiency we have available, keeps narrowing,” she says.

“I think the burnout is due to how much pharmacists care. They have little autonomy over how they spend their time, and want to be doing what they can, what they are trained for, and to follow their purpose; but the pressure on them to do things their management expects, how their management expects, without being heard as to how [they] think it would be best to do, leads to a cycle of frustration.”
Sonia Martinez, RPh, pharmacist-in-charge at Marco Drugs and Compounding in Miami, says exhaustion among pharmacists is widespread and believes it’s even more pervasive among independent pharmacist-owners, due to lower reimbursements and increased regulations.

"Pharmacy practice can feel repetitive, and, candidly, many tasks could be tedious," she says. "As a pharmacist, we are required to juggle many responsibilities almost simultaneously like filling and verifying the accuracy of scripts, answering the phones and questions from insurances, providers or patients. We are also required to fulfill several administrative and or regulatory tasks with little real clinical meaning, adding to the workload burden."

Moreover, in these times of low reimbursements adding additional help—more pharmacists or pharmacy techs—may not be financially sustainable.

Recognizing the Signs

It’s important that people in the field do not ignore the signs of burnout and pay attention to the people they work with. When a colleague snaps back at coworkers or even customers, that’s a telling sign. Albert believes the best way to recognize early signs of burnout both in yourself or in your staff, is by self-monitoring.

“I personally do self-monitoring a la the ‘Sunday night effect.’ On Sunday night, are you totally excited that you’re headed back to work on Monday morning, or are you dreading it? Dread over time shows a pattern of burnout,” she shares. “Anger can be an early warning sign, and apathy typically shows up later. If an employee hits apathy, it might be too late.”

Martinez says pharmacists should check for warning signs in themselves, such as whether they are cynical in one’s comments and thoughts or perceive that there is no progress in their career.

“When one sees that their own state is more pessimistic than usual,” she says. “But this requires a lot of personal knowledge and awareness.”

Mantione says a simple way to check is to ask. “Taking some time to reflect after a busy day could make a bit of a difference,” she says. “Management can check in on staff and listen when they say that they need more help getting everything done.”

She adds that most pharmacists went into the profession because of that desire to help, but find it harder and harder to do that with the resources they have. “We pride ourselves as a profession on being accessible, but that accessibility makes us feel as though we are being pulled in many different directions.”

MARIA MARZELLA MANTIONE, PHARMD

We pride ourselves as a profession on being accessible, but that accessibility makes us feel as though we are being pulled in many different directions.
up while they are gone and the situation will get worse. In so many instances, it is simply unmanageable.”

**Tips to Reduce Burnout**

When it comes to burnout, every pharmacist is dealing with their own personal struggles, so solutions will be different from person to person. The best advice is to find the positive differences that one makes each day and hold onto them, and try your best to let the frustrations go.

Mantione has turned to social media for help. She belongs to a group on Facebook called Pharmacist Moms that provides a platform for women in the field to share ideas, exchange information and support each other.

“Having that kind of tribe can go a long way to improving your mental health and managing stress,” she says.

One helpful trick that Martinez learned from Mark Robert Waldman, neuroscience researcher at Loyola Marymount University, is to yawn purposefully every hour or so. “Based on his research, this gives our brain a break. I call it a mental reboot,” she says. “I also do a daily meditation practice, and that’s what keeps me sane.”

The No. 1 piece of advice from many is that it’s absolutely critical for those in the industry to use every last bit of vacation. “If you don’t use your vacation, you’re leaving something more precious than money on the table. You’re leaving time behind, and time is something you never, ever get back,” Albert says.

She also recommends channeling negative energy into something positive. For those who have a boss, she also recommends discussing concerns and trying to alter responsibilities to more of the work one enjoys.

“I also think it’s a good idea to join associations and groups, and find a mentor,” Albert says. “You need a sounding board for your career. Learn from others. Attend association events and experiences that get you out of your day-to-day office environment and provide you a list of ideas and other ways of working.”

And not all your time needs to be spent doing things that are pharmacy-specific. Sometimes it’s good to get out of one’s comfort zone to reduce burnout. For example, in November, Albert attended the 39th Edition of the Toronto International Festival of Authors and attended a lecture by two historians about Canadian WWII war heroes.

“I was absolutely fascinated by the experience of attending this festival, in another country outside of my own,” she says. “I returned more cool ideas from attending that one-hour session than I have sitting in my office grinding out my work in the past two weeks.”

ASHP’s policy statement on clinician well-being and resilience states that workforce well-being and resilience requires a shared responsibility between individuals and organizations.

“Individuals need to identify and bolster their own resiliency and coping skills and organizations need to meaningfully promote well-being and lead system-level changes to address the external factors contributing to burnout,” Martin says.

“On the individual side, mindfulness and meditation have shown promising and validated improvements; however, this approach doesn’t resonate with everyone,” she adds.

One specific technique has been identified as a means to increase positivity in the minds of a healthcare worker. It is the “three good things” approach.

“You write down three good things that happened that day for 21 consecutive days until the practice becomes a habit.

**Help Is Needed**

Once burnout has occurred, it is difficult to recover. Still, reducing pharmacist burnout isn’t impossible. Martin says there is much that can be done.

ASHP offers a member-only resource center devoted to the topic and offers several webinars on a variety of topics ranging from mindfulness and meditation to leadership strategies.

The National Academy of Medicine has an Action Collaborative to promote clinician and healthcare provider well-being and resilience. Another program is one by the American Medical Association that promotes resiliency, called STEPS Forward. It is designed for physicians and medical students, but many of the concepts can also apply to pharmacists.

“Commitment to addressing and preventing burnout needs to be adopted by everyone from the top level executive to the front line clinician,” Martin says.

**Keith Loria is a business writer living in Virginia.**

**REFERENCES**


Stay informed on issues and events in pharmacy practice

DrugTopics.com

Drug Topics website delivers

- Breaking news
- Commentaries and blogs
- Continuing Education – FREE to Pharmacists and Technicians
- FDA actions
- Pharmacy law
- Digital editions of Drug Topics for easy reference

In-depth analysis

- 2019 Job Outlook
- Provider status update
- Specialty pharmacy update
- Independents carve out their niches

Check it all out at DrugTopics.com

Take our surveys and see what your peers are saying

- Should pharmacists have the authority to prescribe?
- Do pharmacists dig into their own pockets to help pay for prescriptions?
Six Healthcare Technologies Coming in the Next Five Years

Healthcare execs need to lay the cultural foundation today for upcoming technology changes  By Donna Marbury, contributing writer

Experts agree that forecasting the future of healthcare technology isn’t difficult: machine learning, artificial intelligence (AI), and cloud technologies that apply to clinical, workplace, and financial processes will have better and richer incorporation into the industry.

But to get there, healthcare executives need to be laying the cultural foundation today for the technology changes coming in the next decade.

For example, investing in AI over the next five years could cost, on average, more than $30 million per organization, according to a survey of 500 healthcare executives by OptimIQ that was published in November 2018. However, 38% of employers and 20% of health plans believe they would see a return on that investment in four years or less. Ultimately, 94% of respondents see investments in technologies, such as AI, as the clearest route to affordable, accessible and equitable healthcare in the future.

But in order to realize those future possibilities, a culture shift needs to happen in healthcare today, says Tom Lawry, director of worldwide health for Microsoft. “The future of healthcare technology relies more on the culture and framework being created by clinical and business leaders today, he tells Drug Topics.

“What really is going to be needed in the future is not just the breakthroughs in technology, but breakthroughs in creative thinking and the ability of leaders to think differently when redeveloping their processes to leverage the power of the technologies rather than trying to insert these new technologies into a framework,” Lawry says.

Anil Jain, MD, vice president and chief information officer for Watson Health at IBM, says that healthcare organizations will need to shake the stigma of being bureaucratic and slow to adapt so they can be agile enough to adopt future technologies.

“Healthcare organizations need to start to push the agenda that says innovation is important to healthcare. People outside of healthcare view the industry as very conservative, very slow to adapt,” Jain tells Drug Topics. But when you talk to people inside the industry, we all think we’re moving very, very quickly. The key is for these healthcare organizations to get involved in the national debate, at the advocacy level and advising others on what the industry needs, so that movement is made collectively.”

These experts have given their insights on where healthcare technology will be the most impactful in the next decade.

Better Cloud Integration

Although devices collecting digital data are important to healthcare, how that data is shared is the most essential part of the equation, Lawry says.

More than 90% of healthcare organizations are widely using the cloud to host applications, according to a 2017 Healthcare Information and Management Systems Society (HIMSS) survey...
on cloud use. However, the industry is still using the cloud for separate functions, such as clinical apps, data hosting, and backup, and not in a holistic fashion. The survey found that though there is a high level of cloud usage at healthcare organizations, the functionality is still limited.

Use of cloud integration has allowed for data from different healthcare silos to be shared, and as more organizations continue to connect those dots, and Lawry says that it will transform the industry.

"Everyone’s digitizing their data, whether that’s electronic medical records or X-rays. But digitizing data doesn’t do anything other than that. It changes data from one form to another instance," Lawry says. "The transformation that’s brought about by the cloud and bringing that data together allows for all kinds of interesting things. That to us is the number one transformational aspect going forward for the next few years."

**Deeper AI Infusion**

Artificial intelligence has been a part of the healthcare for years, but experts believe in the next decade it will be a regular part of the industry.

A survey of 200 healthcare professionals by Intel Corporation, released in July 2018, found that 37% of respondents were using AI in limited ways, and 54% believe that there will be widespread AI adoption in the next five years.

John Doyle, director of business strategy for Worldwide Health Industry at Microsoft, says, moving forward, we should expect to see AI infused into all aspects of clinical and operational workflow.

"We are early in the journey for cloud and AI adoption today, but we are already starting to see some amazing progress being made, and we expect this continue and with a broader adoption of applied AI in areas such as the clinical interpretation of complex datasets, intelligent medical images, voice integration, and real-time insight of streaming medical devices and sensors data," Doyle says.

As a new generation of consumer-focused services aim to merge patients and consumer journeys, applied AI will disrupt how patients engage with healthcare providers today, Doyle says. "Applied AI has the potential to reduce the complexity of how healthcare data is captured and analyzed, examples of this include how intelligent voice integration and bot technologies are being used during virtual consultations to reduce the time spent entering data by both patients and clinicians, and how pretrained clinical knowledge can be applied at the point of care."

**Infrastructure Upgrades**

The ability for clinicians to meet with patients via web and mobile portals is essential for chronic care management, says Rhonda Collins, DNP, RN, chief nursing officer at Vocera, and founder of the American Nurse Project. "A majority of this country is still rural. So, we need to rely on technology to fill gaps in human connections in healthcare—telehealth will be more important going forward, as infrastructure and technology continue to improve. Hospitals and clinics will need to prepare for a world that technology is making smaller," Collins says.

A 2017 report issued by the Federal Communications Commission found that 50% of U.S. counties house people who both have high occurrences of chronic diseases and a greater need for broadband connectivity. The commission called this “double burden,” and incidents can be as high as 60% in rural counties.

"That makes a remote consultation with a doctor or video chat very difficult, but the situation is improving, and over time, I think at-home remote care will be most valuable in rural areas, where technology use is far more practical than a long drive to see a doctor," Collins says.

As telehealth expansion continues through Medicare reimbursements, patients are still unclear about its availability and use. A survey released by Healthline in August 2018 found that 46% of Medicare Advantage members were unsure if telehealth was an option, and 37% stated telehealth was not offered even though it is.

Collins adds that hospitals are still lacking full-scale wi-fi and consistent cellular service, which impedes integration of telehealth and other mobile health offerings.

"These basic issues make it very difficult to bring technology in to provide extraordinary care and connectivity to all patients everywhere. Infrastructure upgrades are a must, and that should be the focus of many hospitals, so they can leverage great technologies that improve the lives of patients and clinicians alike," Collins says.
Smarter Therapies

Though smart phones, smart watches and other smart devices are being used by consumers, a focus on “smart” hasn’t translated to healthcare solutions, says Kai Patel, MD, MBA, senior vice president of digital health at Flex, a solutions provider that builds intelligent products. “By and large, many healthcare solutions lack meaning. They are not smart,” Patel says. “The data from them is either not collected at all or it is collected, and it stays in some type of local environment which inherently limits the value you can derive from that.”

Patel says in the next decade drug delivery devices such as insulin pens, biologic auto injectors, inhalers, and smart packaging for pills will become commonplace and enhance both clinical and business operations in healthcare. The goal of tracking this data is to add to the landscape of behavioral insights that can help enhance patient care. Patel says the ability to observe how patients use chronic therapies both inside clinical settings and at home or inpatient care settings is enhanced by integrated cloud and artificial intelligence use.

“Most of that technology is already there, so in the next five to 10 years it’s about unlocking that data. Once you can unlock that data, we will really be able to see progress using artificial intelligence and machine learning within those data sets,” Patel says.

Jain says IBM Watson is currently studying concepts around prescribing digital therapies that can be powered by blockchain and artificial intelligence and can be tailored to patients’ behavior. “Wouldn’t it be really interesting if I prescribed an antidiabetes tablet, and I’m also prescribing an app on the patient’s smart phone that makes sure that they stay somewhat adhering to the medication? If they have any side effects, they’re educated about when they should see the doctor or when they could just simply ignore them,” Jain says.

Smarter therapies could also prescribe diets that work in conjunction with medications and give patients more feedback on their progress, he says. “The idea is that we have to go beyond the pill. As a physician, there has to be a better way to virtually have eyes on the patient even when they’re not in my exam room four times a year for 15 minutes.”

Enhanced Personal Medical Care

In the next decade, clinicians will have the ability to use blockchain, machine learning, and artificial intelligence seamlessly to provide specialized care to patients, says Jain.

“The biggest thing is going to be our ability to use these advanced technology enablers to get much better at doing personalized medicine and personalized healthcare with our patients,” Jain says. “Because the back-end healthcare technology is crunching all of their clinical data and administrative data, looking at their genomic profile, looking at their social determinates of health much faster than any human physician or clinician could, and combining that information in a trusted way.”

Jain says that fitness trackers are currently collecting siloed data, but are an important part of the equation when the data can be integrated along with other health determinants. Ultimately, he says more personalized treatments, especially for chronic conditions, would increase adherence to care plans.

“Essentially a clinician will have the ability to say, instead of just practicing in an evidence-based way, we’re going to combine evidence and personalized choices to give patients a much higher likelihood of being successful at the first set of treatments that are offered, instead of going back and forth a few times trying to figure things out,” Jain says.

Mimicking Consumer Tech

Collins says she is hopeful that the workflow technology the healthcare field adopts over the next ten years will match and adapt to technology that people are used to in other areas of their lives. “Before a hospital shift, someone can sit in their cars and buy movie tickets, make dinner reservations, and chat with friends—all from their smart phones. They then enter the hospital for a day’s work, and many times, the technology landscape is entirely different,” Collins says. She fears that antiquated processes and devices in healthcare workplaces will be a deterrent to tech-savvy millennials.

“When millennials go to work at a hospital, we are asking doctors, nurses and care teams to step back 20 years and use landline phones, fax machines, pagers, and overhead calls—all of which downgrade and add complexity to our millennial workforce. They carry a heavy burden every day working with patients in stressful hospital environments, and the very basic technology they’re using only adds to the stress,” Collins says. “Furthermore, we are adding to cognitive loads by forcing them to remember procedures and how to use outdated technologies they are not naturally accustomed to using. So, over time, antiquated technology that doesn’t mirror what is used in our personal life and is not secure will be eliminated. As younger people continue to enter the workforce, many hospitals will be forced to modernize.”

Donna Marbury is a freelance writer in Columbus, OH.
The FDA has fallen back a bit since the blistering pace of new drug approvals it set in 2017. However, 2018 was in no way a lazy year for the agency with more than 40 new molecular entities (NMEs) approved. But 2019 is a different year, and we live in a different time where the federal government endured a long shutdown, one that might possibly be resumed. How many NMEs will be approved this year remains to be seen because the FDA will have to get back up to speed in its approval process.

Here is what you need to know about 18 of the more important new drug approvals since our last roundup in November.

**ULTOMIRIS** (ravulizumab-cwvz, Alexion Pharmaceuticals Inc.)
**Indication:** treatment of adult patients with paroxysmal nocturnal hemoglobinuria.

**Dosage:** Intravenous infusion only. ≥40 kg to < 60 kg = 2.400 mg leading, 3.000 mg maintenance; ≥60 kg to < 100 kg = 2.700 mg leading, 3.300 mg maintenance; ≥100 kg = 3.000 mg leading, 3.600 maintenance

**Contraindication:** Patients with unresolved Neisseria meningitidis infection.

**ELZONRIS** (tagraxofusp-erzs, Stemline Therapeutics)
**Indication:** Treatment of blastic plasmacytoid dendritic cell neoplasm in adults and in pediatric patients age 2 and older.

**Dosage:** Intravenously at 2 mcg/kg over 15 minutes once daily on days 1 and 5 of a 21-day cycle. First cycle recommended in inpatient setting.

**Contraindication:** None

**Warning:** Capillary leak syndrome, including life-threatening and fatal cases, has been reported.

**ASPARLAS** (calaspargase pegol-mknl, Servier)
**Indication:** Asparagine specific enzyme component of multiagent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia in pediatric and young adult patients age 1 month to 21 years.

**Dosage:** 2,500 units/m² intravenously, no more frequently than every 21 days

**Contraindication:** Serious hypersensitivity reactions to pegylated L-asparaginase; serious thrombosis during L-asparaginase therapy; serious pancreatitis related to previous L-asparaginase treatment.

**NUZYRA** (omadacycline, Paratek)
**Indication:** Adult patients with community-acquired bacterial pneumonia (CAPB) or acute bacterial skin and skin structure infections (ABSSI).

**Dosage:** CAPB—Day 1: Intravenous infusion 200 mg/60 min or 100 mg/30 min twice; Maintenance: Intravenous Infusion: 100 mg/30 min or 300 mg orally once daily. ABSSI—Day 1: Intravenous infusion 200 mg / 60 min or 100 mg/30 min twice, with maintenance infusion of 100 mg/30 min or 300 mg orally once daily; or if using oral tablets only, 250 mg orally once daily on day 1 and 2 with maintenance of 300 mg orally once daily

**Contraindication:** Known hypersensitivity to omadacycline, tetracycline-class antibacterial drugs, or any excipient in Nuzyra

**REVCOVI** (elapegademase-lvr, Leadiant Biosciences)
**Indication:** Adenosine deaminase severe combined immune deficiency.

**Dosage:** See prescribing information for patients transitioning from Adagen. Starting dose for treatment-naïve patients is 0.4 mg/kg of ideal body weight in 2 intramuscular supplements (0.2 mg/kg twice per week) for minimum of 12 to 24 weeks.

**Contraindication:** None.
**PRODUCT ROUNDUP**

**TEGSEDI** (inotersen, Akcea Therapeutics)
**Indication:** Polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.
**Dosage:** 284 mg subcutaneous injection once weekly.
**Contraindication:** Platelet count less than 100 x 10⁹/L, history of acute glomerulonephritis caused by inotersen, history of hypersensitivity reaction to inotersen.

**TALZENNA** (talazoparib, Pfizer)
**Indication:** Adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer.
**Dosage:** 1 mg dose orally.
**Contraindication:** None.

**XOFLUZA** (baloxavir marboxil, Genentech)
**Indication:** acute uncomplicated influenza in patients age 12 and over, within 48 hours of first symptoms.
**Dosage:** 40 mg for 40 to 80 kg body weight; 80 mg for more than 80 kg.
**Contraindication:** History of hypersensitivity to baloxavir marboxil or any of its ingredients.

**LORBRENA** (lorlatinib, Pfizer)
**Indication:** Patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small-cell lung cancer whose disease has progressed on crizotinib, alectinib, or ceritinib.
**Dosage:** 100 mg orally once daily.
**Contraindication:** Concomitant use with strong CYP3A inducers

**YUPELRI** (revefenacin, Mylan)
**Indication:** Patients with chronic obstructive pulmonary disease.

**Dosage:** One 175-mcg vial (3 mL) once daily.
**Contraindication:** Hypersensitivity to revefenacin or any component of it.

**GAMIFANT** (emapalumab-lzsg, Sobi)
**Indication:** Patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance of conventional HLH therapy.
**Dosage:** 1 mg/kg as an IV infusion over 1 hour twice per week; administer dexamethasone concomitantly with this drug.
**Contraindication:** None.

**DAURISMO** (glasdegib, Pfizer)
**Indication:** Newly-diagnosed acute myeloid leukemia (AML) in adult patients 75 years old or older who have comorbidities that preclude use of intensive induction chemotherapy.
**Dosage:** 100 mg orally once daily.
**Contraindication:** None.

**FIRDAPSE** (amifampridine, Catalyst Pharmaceuticals)
**Indication:** Treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults.
**Dosage:** The recommended starting dosage is 15 mg to 30 mg daily taken orally in divided doses (3 to 4 times daily). Starting dosage is 15 mg daily for patients with renal impairment, hepatic impairment, and in known N-acetyltransferase 2 poor metabolizers
**Contraindication:** History of seizures or hypersensitivity to amifampridine or another aminopyridine

**VITRAKVI** (larotrectinib, Bayer and Loxo Oncology Inc)
**Indication:** Treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have no satisfactory alternative treatments or have progressed following treatment.
**Dosage:** 100 mg orally twice daily for patients with body surface area at least 1.0 m²; 100 mg/m² orally twice daily for pediatric patients with body surface area less than 1.0 m².
**Contraindication:** None.

**XOSPATA** (gilteritinib, Astellas)
**Indication:** Adult patients with relapsed or refractory acute myeloid leukemia with an FLT3 mutation.
**Dosage:** 120 mg orally once daily.
**Contraindication:** Hypersensitivity to gilteritinib or any of the excipients. Anaphylactic reactions have been observed in clinical trials.

**SIKLOS** (hydroxyurea, Medunik USA)
**Indication:** Pediatric patients with sickle cell anemia, 2 years of age and older, with recurrent moderate to severe painful crises.
**Dosage:** 20 mg/kg once daily. Monitor blood counts every 2 weeks. May be increased by 5 mg/kg/day every 8 weeks or sooner if a severe painful crisis occurs, until a maximum tolerated dose or 35 mg/kg/day is reached if blood counts are in an acceptable range.
**Contraindication:** Previous hypersensitivity to hydroxyurea.
How to Prevent Medication Errors

Pharmacists must cultivate a culture of safety, training to protect patients

By Jason Poquette, RPh, contributing writer

First, do no harm. We’ve all heard these words from the Hippocratic Oath. But from the sounds of it, we might not be listening very well. A shocking 2016 report out of Johns Hopkins indicates that medical error is now the third leading cause of death in the United States. While all of these fatalities are not medication-related errors, many are.

Medication errors can happen in any setting, but I am especially sensitive to the challenge of preventing errors in a retail pharmacy where there are so many competing priorities and constant distractions. My advice, therefore, is especially aimed at my brothers and sisters on the bench.

Create a Culture of Safety
Preventing errors has to become the very flavor and language of your pharmacy. When you travel, you learn about different cultures by immersing yourself in their language, food, customs, and style. Visitors to your pharmacy should likewise get a sense that “safety” is your custom, the way you live and move. You do this by talking about it frequently, sharing examples, telling stories, and being a champion of error-prevention yourself.

Don’t Skimp on Training
I believe the training programs in most of our organizations are inadequate for the demands of a busy, distracting retail pharmacy. Sure, we expect our personnel to have a baseline drug knowledge. But where we fall short are the computer-training, problem-solving, communication-techniques, and people-skills needed to efficiently work together as a team. Untrained people get flustered and then make mistakes. Well-trained people work more efficiently. Good training brings all the parts together. And this requires an investment in great trainers and training programs.

Require Order
I urge you to have a zero-tolerance policy for chaos in the pharmacy. The mantra I communicate frequently to my team is: “Busy is good, chaos is not.”

Chaos is usually the result of one or more good people making one or more bad choices.

For example, we might cut corners to try and speed things up to an unsafe pace. Baskets in the work flow might get disorganized. Patients might be promised unrealistic timelines, thus putting inappropriate pressure on the team. Someone might get flustered, distracted, or upset. You need a leader, ideally the pharmacist, to exude a calming influence and to insist on maintaining decency and order in the work flow steps.

Get in the Zone
I tell my pharmacists to picture themselves in a courtroom every time they verify a prescription, trying to explain to a jury why they allowed that prescription to go out. A scary thought—but we need sobering reminders of just how serious our job is.

Take a breath. Read the label carefully. Think. You must train yourself to look for all of the possible errors that may be in front of you. Is this a commonly confused drug or dosage form? Does the dosing make sense? Does the prescription seem reasonable for this patient given their age, gender, and history? There’s simply no checklist that will replace the importance of getting your head in the game. Every time. Every single prescription.

Jason Poquette, RPh, is a director of Outpatient and Specialty Pharmacy Services at St. Vincent Hospital in Worcester, MA.
NEW DRUG REVIEW

Dsuvia (Sufentanil) for Acute Refractory Pain

Sublingual form approved for short-term use

By Alison Geary and Kathryn Wheeler, PharmD, BCPS

The FDA approved sublingual sufentanil (Dsuvia, AcelRx Pharmaceuticals) in November for management of severe acute pain refractory to alternative treatments in adults being treated in a medically supervised healthcare setting. Sufentanil is a relatively selective full agonist of the mu-opioid receptor, which provides analgesia and sedation.1

Efficacy

The efficacy of sublingual sufentanil was assessed in three Phase 3 clinical trials.2-4 SAP301 was a multicenter double-blind placebo-controlled trial with 161 participants that compared 30 mcg of sublingual sufentanil to placebo for postoperative pain following abdominal surgery. The primary outcome was the summed pain intensity difference over 12 hours (SPID12), which uses a score from 0 (no pain) to 10 (worst possible pain) to calculate the difference in pain intensity over the 12 hours. Sublingual sufentanil showed a statistically significant greater difference in SPID12 compared to placebo.

SAP302 was an open-label study with 76 participants assessing safety and efficacy of 30 mcg of sublingual sufentanil for moderate-to-severe acute pain in emergency room patients with obvious trauma or injury. The primary outcome was the summed pain intensity difference over 1 hour (SPID1). Pain was measured at baseline and every 15 minutes over the hour and then hourly for 5 hours. The study demonstrated a decrease in the pain intensity of participants during the study period.

SAP303 was a multicenter open-label trial with 140 participants assessing safety and efficacy of 30 mcg sublingual sufentanil for postoperative pain. Similar to SAP302, the primary outcome is the SPID12. Results demonstrate a decrease in pain intensity of participants during the 12-hour study period.

Safety

The safety of sublingual sufentanil was assessed in a total of 646 patients in both controlled and uncontrolled studies, including SAP301, SAP302, and SAP303.1 In the combination of all three SAP studies, two patients in the sublingual sufentanil groups reported a severe adverse event. One patient in the SAP302 study experienced angina pectoris, and one in the SAP303 study experienced an acute stroke.1,4 Sublingual sufentanil was well-tolerated by patients, Adverse effects occurring in more than 10% of patients included nausea and headache.2-4 Serotonin syndrome has been reported in patients taking sufentanil and serotonergic drugs.

Sublingual sufentanil should not be used for more than 72 hours as it has not been studied beyond this time frame. Its use in pediatrics is not recommended because safety and efficacy in this population have not been established. Geriatric patients should be monitored closely due to risk of central nervous system and respiratory depression. Use caution in pregnant patients as prolonged use of opioids can lead to neonatal opioid withdrawal syndrome.

Dosing

Sublingual sufentanil is a single-use tablet that must be administered by a healthcare professional in a certified medically supervised healthcare setting. The tablet should be delivered to the space under the tongue using a prefilled applicator to limit accidental exposure to the healthcare professional and to ensure proper placement. The recommended dose of sublingual sufentanil is 30 mcg as needed. The maximum cumulative daily dose is 12 tablets (360 mcg) with a minimum of 1 hour between doses.1
Hard Work Is Inevitable, But Burnout Is Not

God didn’t waste any time telling us that we must work for a living. Right after God created the heavens and earth, He tells us it is our turn to get to work:

*By the sweat of your brow you will eat your food until you return to the ground, since from it you were taken; for dust you are and to dust you will return.*

Genesis 3:19 New International Version

Work isn’t meant to be fun, but when it turns into drudgery, we must do something. I feel there are three stages to any pharmacist’s career:

**Stage 1:** “Show me the money” Most new pharmacists fit here. With student loans exceeding $100,000 for most, they need to get moving to pay down this dark cloud over them. Once student loans are under control, they accumulate more debt through car payments, house payments, getting married, and starting a family. This group is looking for the maximum salary and other benefits.

**Stage 2:** “Show me the schedule”: After Stage 1, many pharmacists fall into this group as family life takes hold. This stage includes pharmacists who have been practicing between five and 20 years. Salary is important to fund the family lifestyle, but the hours of family time become more important. “Sorry boss, I can’t work on Sunday. We’re going camping.”

**Stage 3:** “Show me the conditions”: This stage is where my wife, Denise, and I fit into. The house is paid off, and the kids are educated and on their own. We drive cars with more than 100,000 miles because we don’t have anyone to impress. We hate debt and are busy stuffing our 401ks for eventual retirement. The salary and schedule are not nearly so important as good working conditions. Our group loves the patient interactions and gets involved in patient care. We’re looking for adequate technician help, less prescription volume, and most of all, less supervision and more freedom to practice our profession.

When the wants of the pharmacist in those stages are not met, burnout occurs. Burnout is a chronic condition like hypertension and type 2 diabetes. Like those disease states, it is frequently diagnosed by someone else. The three major dimensions of burnout are cynicism, which is manifested by negative job and workplace attitude; emotional exhaustion, which is feeling emotionally depleted, apathetic, and indifferent; and ineffectiveness, defined as devaluing one’s work, or new tasks that are meaningless.

Stress, however, is an acute condition, usually causing emotional exhaustion. Stress includes somatic symptoms, such as a racing heart, elevated blood pressure, and a good bit of sweating. The individual pharmacist is aware of stress and can easily diagnose it. But we don’t always identify burnout in ourselves when it happens. The symptoms of burnout—hopelessness, cynicism, detachment from others—might take months to surface. If someone close to you points out changes in your attitude or behavior that are typical of burnout, listen to that person.

But then what do you do? Maybe you need to think about changing something. Pharmacists don’t quit their jobs, they quit their bosses.

Steve Jobs said: “I have looked in the mirror every morning and asked myself: ‘If today were the last day of my life, would I want to do what I am about to do today?’ And whenever the answer has been ‘No’ for too many days in a row, I know I need to change something.” Perhaps we all need to take that advice to heart as we wipe the sweat from our brows.
Contemplating the Sale of Your Pharmacy?
Select the largest, most experienced advisor to assist you.

18 YEARS EXPERIENCE
Successful completion of 500 sales

KNOWLEDGE and EXPERIENCE
Six principals advising our clients

NATIONAL COVERAGE
Coast-to-coast personalized service

STRAIGHT TALK
Reality-based valuations; best outcomes

COMPLETE CONFIDENTIALITY
At all times, for your benefit

COMPETITIVE FEES
Pay when you sell; no upfront fees

We Work Only For You!

MARKETPLACE CAN WORK FOR YOU!
Reach highly-targeted, market-specific business professionals, industry experts and prospects by placing your ad here!

CONNECT with qualified leads and career professionals
Post a job today

Joanna Shippoli
RECRUITMENT MARKETING ADVISOR
(800) 225-4569, ext. 2615 • joanna.shippoli@ubm.com

www.modernmedicine.com/physician-careers

www.buy-sellapharmacy.com  |  877-360-0095
SELLING YOUR PHARMACY?
WHAT YOU DON'T KNOW CAN LOWER YOUR SALE PRICE.

EXPERTISE
Work with a licensed and insured broker, who has personally sold and closed over 140 pharmacy transactions in 42 states.

ADDED VALUE
Our proven, confidential, proprietary process means a higher price, less stress and lower risk for you.

FREE CONSULTATION
Call 888.808.4774 before disclosing any information to a potential buyer.

Daniel J. Lannon, RPh, Broker
Representing pharmacy owners nationwide.

Call 888.808.4RPH (4774)
Text 651.769.4932
Email dan@pharmacycbs.com
Web pharmacycbs.com

CREATE FUTURE VALUE.
Call today for a free Cost of Goods Sold-Profit Analysis.

Leverage branded content from Drug Topics to create a more powerful and sophisticated statement about your product, service, or company in your next marketing campaign.

Contact Wright’s Media to find out more about how we can customize your acknowledgements and recognitions to enhance your marketing strategies.

For information, call Wright’s Media at 877.652.5295 or visit our website at www.wrightsmedia.com

© 2018 Pharmacy Consulting Broker Services.
Selling Your Pharmacy?

Maximize Your Value

Minimize Your Worry

HAYSLIP & ZOST

Pharmacy Sales Experts Ready to Help You!

www.RxBrokerage.com

Tony Hayslip, ABR/AREP
713-829-7570
Tony@RxBrokerage.com

Ernie Zost, RPH
727-415-3659
Ernie@RxBrokerage.com

Call Hayslip & Zost Pharmacy Brokers LLC for a free consultation. We have helped hundreds of independent pharmacy owners nationwide get the maximum value for their pharmacies. For more information about us, please visit our website.