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FIRVANQ™ (vancomycin hydrochloride) for oral solution

THERE’S AN EASY-TO-RECONSTITUTE ORAL VANCOMYCIN SOLUTION FOR

HERE...

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.

**Reference:** 1. FIRVANQ™ Prescribing Information. Wilmington, MA: CutisPharma, Inc; 2018.
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:
- Oral administration of 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. 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.

- Otoxicity has occurred in patients receiving vancomycin hydrochloride. It may be transient or permanent. Assessment of auditory function may be appropriate in some instances.

- 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 (HORV), including permanent loss of vision, occurred in patients receiving intracamer al 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%).

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

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

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

In addition to the information presented above from clinical trials, the following adverse reactions have been identified during post-approval use of vancomycin hydrochloride:

**Otoxicity:** Hearing loss, vertigo, dizziness, and tinnitus have been reported.

**Hematopoietic:** Reversible neutropenia, usually starting 1 week or more after onset of intravenous therapy with vancomycin or after a total dose of more than 25 g, has been reported. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocytopenia has been reported.

**Miscellaneous:** Anaphylaxis, drug fever, chills, nausea, eosinophilia, rashes (including exfoliative dermatitis), Stevens-Johnson syndrome, toxic epidermal necrolysis, and vasculitis have been reported with the administration of vancomycin.

A condition has been reported with oral vancomycin that is similar to the IV–induced syndrome with symptoms consistent with anaphylactoid reactions, including hypotension, wheezing, dyspnea, urticaria, pruritus, flushing of the upper body (“Red Man Syndrome”), pain and muscle spasm of the chest and back. These reactions usually resolve within 20 minutes but may persist for several hours.

### 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™ in the refrigerator when not in use.
  - Discard reconstituted solutions of FIRVANQ™ after 14 days, or if it appears hazy or contains particulates.

This is a brief summary of information from the prescribing information and does not include all of the information from the full PI. See the complete PI at www.FIRVANQ.com.

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. Wilmington, MA 01887 USA

Rev. 2/2018
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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.
As the opioid crisis blazes a deadly trail across America, one of the most at-risk demographics is the working age population—those between ages 25 and 54. The effects of this crisis are well known: emotional and financial devastation for individuals and their families, overwhelming demands on first responders and social service providers, and mounting losses for businesses that depend on this diminishing workforce. The CDC estimates that the total cost of opioid misuse and abuse in the United States is nearing $80 billion a year—reflecting the costs of employee healthcare, lost productivity, and workplace injury.

Despite this bleak outlook, there is hope. For employers and plan sponsors, patient data provides a rich resource that can help address the problem of opioid misuse and addiction among their health plan members.

As part of the administrative service they provide, health plans may permit plan sponsors to access a broad snapshot of the patient’s pharmacy and medical data. This means plan managers can systematically identify members who are both new and chronic opioid users, monitor behavior, and provide relevant outreach and intervention.

For example, a plan manager can set parameters to identify members who have continually used opioids for more than a threshold number of days—often an indicator that they will become long-term users without some type of intervention. A plan manager can also set up alerts so they know when members are filling multiple opioid prescriptions at different pharmacies—a pattern that can point to drug abuse or misuse.

Detecting misuse or risk of misuse, however, is only part of the battle. To effectively treat any individual struggling with opioids, it’s crucial to understand the path that brought them to opioid use in the first place. It is critical to engage the family and the patient to understand how usage started, and the issues that are driving usage today.

Pharmacy and medical data are of great use here, too. These data sets reveal a chronology of diagnoses and treatments that help pinpoint the causal factors of a plan member’s opioid use, such as long-time chronic pain versus a recent injury. A persistent user who has been taking opioids for 60 days or more requires a different approach to education or intervention than a person who was newly prescribed opioids.

Case managers can use this information to better understand a patient’s situation from a medical and psychological perspective and develop an effective communication plan. Some patients are well-managed with pharmacy-level utilization review alone, but others require more information and outreach to make progress and improve the patient’s well-being. By taking this hands-on approach with an understanding that long-term behavior is not changed instantly, managed care providers can develop personalized treatments to drive success.

Such treatment plans often involve working one-on-one with each patient to connect them to the proper care professionals such as social workers and physical therapists, who can help them address the underlying causes of opioid misuse and guide them to other pain management therapies like acupuncture or medical cannabis.

Health plans have the power to facilitate positive change and arrange for comprehensive care to address all aspects of opioid dependencies.

Managed care plans already have a framework to optimize legitimate opioid use and help safeguard against misuse. The valuable data we have are an essential lever in that process. Let’s pull that lever.

“Patient data provides a rich resource that can help not just react to, but stem, the problem of opioid use and addiction.”

Bartley Bryt, MD, is chief medical officer of Brighton Health Solutions, where he determines the clinical vision for both the Create and Magnacare health plan products.
Drug Take Back Day Sets New Record

On April 27th, the Drug Enforcement Administration (DEA) collected and destroyed more than 469 tons of unused or expired prescription medications at local, state, tribal, and federal partnership sites.

More than 6,400 collection sites participated in the 17th annual event, bringing the DEA’s total collection since the fall of 2010 to 11,816,393 pounds, or 5,908 tons.

“The ever-increasing public support and continuously growing numbers of partners and collection sites are a true testament to the value of DEA’s National Prescription Drug Take Back program,” says Uttam Dhillon, the DEA’s acting administrator. “Just as DEA and our law enforcement partners are committed to ending the opioid epidemic, our communities recognize that this is a pervasive and heartbreaking crisis. DEA Take Back Day gives every American a way to help by simply cleaning out their medicine cabinets.”

Since the National Rx Drug Take Back Day’s inception, the events have been extremely successful at removing unused drugs from homes and at raising awareness of their link to addiction and overdose deaths, DEA says.

Public demand for safe and secure drug disposal has resulted in an increase in the number of drop boxes for unused prescription drugs at law enforcement facilities, pharmacies, and elsewhere, the DEA says.
Civica Rx and Xellia Pharmaceuticals have announced a partnership wherein Xellia will manufacture two antibiotic medications that are routinely in short supply. Xellia will manufacture vancomycin and daptomycin for Civica’s member health systems.

Civica Rx, a nonprofit established in 2018 to combat chronic generic drug shortages, is aiming to stabilize the supply of antibiotics, anesthetics, cardiac medications, pain management medications, and other essential sterile injectable medications through a three-pronged product supply strategy. More than 800 hospitals have joined Civica.

Xellia, headquartered in Copenhagen, Denmark, produces its own active pharmaceutical ingredients and finished injectable drug products for serious and often life-threatening bacterial and fungal infections. With this new agreement, the company is expanding its manufacturing and sales capabilities within the United States. Xellia is the first of several generic drug manufacturers that will collaborate with Civica. The company, formed by a number of health systems across the United States, expects to partner with other manufacturers that have FDA-approved manufacturing facilities with the capacity to provide the number of generic drugs Civica will need for its member systems. Civica says that it will be developing and acquiring abbreviated new drug applications (ANDAs) for generic drugs and working with contract manufacturing organizations to produce the medications, as well as acquiring and building Civica manufacturing facilities using these ANDAs.

The National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS) issued a joint statement expressing their frustration over the release of HHS’s final drug pricing rule for Medicare and Medicaid. The final version of the rule fails to reform pharmacy direct and indirect remuneration (DIR) fees.

“We are disappointed and frustrated that this final rule fails to finalize pharmacy DIR reform as proposed, to the detriment of seniors and community pharmacies,” the statement says.

The two groups contend there are misinterpretations of some terms used in the Medicare program related to pharmacy reimbursement and drug pricing.

In turn, these misinterpretations have led to “these claw-backs, and ultimately to higher out-of-pocket drug costs for patients and increased costs for the government,” according to the statement.

“Our organizations have been joined by many pharmacists, pharmacy stakeholder groups, patient advocacy organizations, patients, and members of Congress in advocating that all pharmacy price concessions be included at the point of sale—or eliminated altogether—to provide senior patients with lower costs and pharmacies with more certainty.”

The proposed rule noted the recent 45,000% increase in pharmacy price concessions, which NCPA and NACDS say is unsustainable. “Pharmacies are in a tenuous situation, and our organizations are exploring all options to accomplish desperately needed reforms to pharmacy DIR. It is necessary for community pharmacies and for the benefit of seniors that this reform take effect as soon as possible.”

NACDS and NCPA represent more than 62,000 pharmacies drug stores and supermarkets or mass merchants with pharmacies.

Gilead will donate 2.4 million bottles of Truvada to the CDC over the next 11 years.

Walgreens is partnering with the National Council for Behavioral Health and the APHA to offer mental health first-aid training. Pharmacists and team members at select Walgreens locations will learn health literacy, the risk factors and warning signs for mental health and addiction, and strategies for managing patients in both crisis and noncrisis situations.
44 States Join Lawsuit Alleging Price Fixing for Generics

State prosecutors from 44 states have joined a lawsuit filed in Connecticut that claims several of the largest makers of generic drugs conspired to inflate or manipulate prices on more than 100 products.

“We have hard evidence that shows the generic drug industry perpetrated a multibillion-dollar fraud on the American people,” Connecticut Attorney General William Tong. The suit says that prices for generic drugs were inflated by more than 1,000% in some cases.

The companies named in the suit include Teva, Pfizer, Novartis, and Mylan.

The suit alleges that these generic drug makers had an agreement not to compete with each other and to avoid competition that would push drug prices down.

Company executives were said to meet and conspire on drug prices at industry events, parties, and golf outings to reduce the amount of written communications.

The Association for Accessible Medications (AAM), the trade group for generic drug makers, issued a statement in response: “We have established procedures and policies to help ensure compliance with the antitrust rules at our board meetings and all other AAM meetings. We will continue to assess our antitrust policies because we are committed to the idea that robust competition is the key to providing affordable and accessible medicines to patients while also constraining health care costs.”

Teva denies the allegations. “Teva continues to review the issue internally and has not engaged in any conduct that would lead to civil or criminal liability,” the company says in a statement. ■

— Valerie DeBenedette, managing editor

FDA to Launch Drug Supply Chain Security Act Regional Pilot Project

One of blockchain’s potential applications to the pharmacy industry, the Drug Supply Chain Security Act, will be tested in August in a multiregional pilot project studying the use of the technology to track intra- and inter-healthcare system medicine transfers.

Blockchain has been touted for its potential to reduce fraud and increase security within pharmacy and has even been implemented into programs like RemediChain that help legally redistribute unused cancer medications.

The pilot will be conducted in health system transfers in North Carolina, Indiana, and Tennessee, and will include various technology applications. The FDA has selected Good Shephard Pharmacy and RemediChain, Rymedi, Temptime/ Zebra Technologies, Indiana University Health, WakeMed Hospitals and Health, the Center for Supply Chain Studies, and the Global Health Policy Institute. Good Shephard Pharmacy and RemediChain will apply the solution to medicine transfers in their approach of connecting donors with patients unable to afford specialty and rare disease medications.

Rymedi’s blockchain platform will ease the integration of upstream supply data between the manufacturer and linking of patient medicine use and outcomes data for high-value regulatory-grade real world evidence.

Temptime, which is now a part of Zebra Technologies, will apply sensors to provide temperature monitoring that is essential for many specialty medicines.

The Center for Supply Chain Studies and the Global Health Policy Institute at the University of California San Diego will provide the design and evaluation support to optimize the pilot’s impact on policy and industry standards development.

Indiana University Health, the largest hospital network in Indiana, will work with WakeMed Health and Hospitals in Raleigh, NC, to implement the consortium solution to track the specialty medicines across provider locations. ■

— Valarie DeBenedette

Facebook Takes Steps to Reduce Vaccine Misinformation

The social media giant is aiming to reduce the spread of harmful vaccine misinformation by reducing the ranking of groups and pages that promote such misleading or wrong information.

The groups will not be removed from the site, but will be excluded from Facebook’s news feeds and search functions. Personal accounts will not be targeted nor removed, according to CNN.

— Jill Sederstrom

CVS Health Buys Premier

CVS Health purchased Premier Pharmacy Inc. for $22.5 million plus an additional $20 million for inventory. The move increases CVS Health’s specialty pharmacy business by 367 hospitals in 66 health systems.

The move was partially motivated by Premier Pharmacy’s desire to leave the specialty pharmacy space, citing significant dynamic market shifts. Instead, Premier will increase its focus on providing better service to its member health systems. ■

— Valarie DeBenedette
Contemplating a ‘Black Swan’ Scenario

Adam J. Fein, on the future of rebates  

By Kayt Sukel, contributing writer

Has specialty pharmacy reached an “inflection point” that will change the industry model? What lies ahead for the specialty pharmacy industry?

These are the questions that Adam J. Fein, PhD, CEO of the Drug Channels Institute, addressed during an April panel discussion titled, “Specialty Pharmacy Industry Outlook: What’s Next?” at the 2019 Asembia Specialty Pharmacy Summit in Las Vegas.

Fein, often called on to discuss the future of specialty pharmacy, opened the panel by stating the industry was at an important “turning point,” referring to the HHS proposed rule to eliminate safe harbor protections for rebates paid by drug manufacturers to pharmacy benefit managers (PBMs), Medicare Part D plans, and Medicaid managed care plans.

“We are at an inflection point that will potentially change the entire commercial model of the pharmaceutical industry for the first time in a generation,” he says. “We are potentially on the verge of moving to a world without PBM rebates—which will lead to a total change in the way we do business.”

To understand what this new world might bring, Fein says, it is important to consider the factors that have shaped the industry. In 2014, drug list prices were increasing by double-digit rates, he adds. “Can you think of any other thing you buy where the same thing goes up 13.5% over one year and then another 11.9% the next?”

“When industry executives like Mylan’s chief executive officer Heather Bresch were called to account by the U.S. government to explain the skyrocketing costs, they said that they only received 45 cents on the dollar—the other 55 cents were going to other players. That shined a light on how rebates and kickbacks were influencing drug pricing—and hurting patients,” he says.

In his talk, Fein addressed what he called the “gross-to-net bubble.” In the past few years, there has been a significant difference between list and net prices, or the cost of drugs after discounts and rebates. Such a bubble is simply unsustainable, he says.

“In 2013, $83 billion in rebates and other discounts were provided by manufacturers off the list price—by last year, that number was $166 billion,” he adds. “These things have essentially created a crisis for patients, who are paying out-of-pocket costs, their copays, or deductibles, based on the list price.”

Given these issues, it’s not surprising that HHS proposed an anti-rebate rule—which many believe will be finalized in the next few months. If it is finalized, Fein says, it will “blow up the entire system” and require everyone in the specialty pharmacy industry to rethink how they do business.

Even if the rule is quashed, the issues it raises still need to be addressed. Too much has been revealed about the inner workings of the industry, where the sick subsidize the healthy, he says.

“If approved, the way that plans and premiums manage specialty pharmacy would change,” he adds. “We need to start focusing on the true net cost of drugs. You may see many brand name drugs vanish from formularies. And you will probably see benefit design begin to change. There will be a world of greater competition.”

This kind of previously unfathomable “black swan” scenario, Fein says, will require physicians and patients to make direct cost and value trade-offs differently than they do at present.

“There will be an extensive amount of usage management. There will be a lot of formulary management,” he says. “You’ll see specialty pharmacies navigating a whole new world with their patients—and the rationale for the gross-net-bubble will disappear.”

On the precipice of such radical change, the industry will have to rethink the way it has traditionally done business, he adds. But, as with any other time of great uncertainty, there is the potential for remarkable opportunity.

“This is an exciting time. It’s a dynamic time. It’s a time of greater change than I’ve ever seen in this industry,” Fein concludes. “With all this change, with all this trouble, with all this complexity, try to stay positive.”
IN MY VIEW

By Peter Vlasses, PharmD, DSc(Hon), FCCP

ACPE: It’s the Quality, not Quantity, of PharmD Programs

“Educational program accreditors do not exist to control the employment markets of their associated professions.”

In my 20 years as executive director of the Accreditation Council for Pharmacy Education (ACPE), and more so recently, we have been asked why we don’t call a moratorium on opening new pharmacy schools, or why we don’t better control the number of students enrolled and graduating from accredited programs each year. Or, why isn’t ACPE acting as the “gatekeeper” for new schools and pharmacists entering the marketplace to help manage and preserve jobs and salaries in the industry?

We live in a free market society. When I started in my position, pharmacy had 78 accredited schools, and we were graduating approximately 7,000 students a year. Because projections were made of an upcoming pharmacist shortage due to an aging population with increasing medication needs, existing colleges and schools of pharmacy expanded their class sizes and/or opened branch campuses. Many new schools began to apply for accreditation.

Now we have 143 accredited schools and are graduating approximately 14,500 students per year. Until recently, this dramatic increase in graduates has been accommodated by the job market, with almost all students having employment options, although lately, not always in their preferred geographic area. As the urban job market started to saturate, enrollment numbers to pharmacy programs have begun to take a downturn.

This is the type of market response I learned about years ago in economics. Had ACPE acted to limit the growth of existing programs or new ones, many of the new graduates would have been robbed of the opportunity to practice pharmacy.

Educational program accreditors do not exist to control the employment markets of their associated professions. ACPE’s standards are based on quality, not quantity. Our focus is making sure students have the best information to make career and program decisions at the time of application.

Unfortunately, sometimes a market shifts quickly before a cohort of students graduate from a four-year program. As ACPE monitors licensing exam performance and the employment of graduates, it is important to ensure students are properly informed about these market shifts. We have noted that program sizes have begun to “right size” on their own by accepting fewer students and ensuring acceptance of only qualified candidates, and by closing branch campuses. These actions are the responses seen in a free market system.

By monitoring enrollments, graduation and employment rates, and information available to applicants and students, we as accreditors allow the market to respond based on the availability of relevant information. However, if a program continues to accept students when their graduation, licensing, and employment rates fall, we can (and have) engaged its leaders in serious conversations about their need to better inform prospective students about these rates and/or adjust program size. If the pharmacy program is unable to meet ACPE accreditation standards, that is a different story that requires different considerations.

I have great compassion for those pharmacy students who struggle to find employment after graduation while trying to manage substantial student loan debt. On the other hand, I believe there are jobs for pharmacists in rural America for people willing to relocate, even for a few years until the job market opens up and as more baby boomers retire.

Although I feel bad for those students facing job placement difficulties, ACPE is unable to change its review process that would either close programs or stop accrediting new programs as a means of protecting them.
A reality check is in order. I recently attended a California State Board of Pharmacy meeting. On the agenda that day was a discussion of pharmacists’ old nemesis, Tech-Check-Tech, which was soundly defeated in 1996 by angry pharmacists.

At my last pharmacist position, the company had just brought in a new pharmacy system that conveniently scanned the drug bottle for accuracy and allowed technicians to handle all prescription fillings. The pharmacist would read the drug bottle label to see, for example, if the pills were a “lavender colored tablet with VT3M imprinted on the tablet.” If so, then it was OK to sell.

There has been a lot of talk that pharmacy schools will soon outnumber McDonald’s. My point is that pharmacists are not in that much demand and, if Tech-Check-Tech passes, there will be even less demand.

With that being said, I believe it is time for the California Pharmacists Association (CPhA) to begin creating the next era for this great profession, and it starts with the increasing legalization of medical and recreational marijuana.

If the Marijuana Dispensary Law is passed in the upcoming election, California pharmacists must be ready to seize the opportunity to be at the forefront of this outstanding new occupation.

I recently attended a meeting with Fred Mayer, RPh, president of Pharmacists Planning Service, Inc. He and I met with Stephen Woods, chief of the Food and Drug and Radiation Safety division, and Asif Maan, PhD, chief of the Office of Medical Cannabis Safety of the California Department of Public Health. (Mayer is a member of the Editorial Advisory Board of Drug Topics.)

I left that meeting feeling that pharmacists have a huge opportunity to benefit from medical marijuana and cannabis, if all goes well with the Medical Cannabis Dispensary Program. This program will set up dispensaries in every county in California where medical marijuana is legalized.

First, and foremost, a pharmacist must be available and partially responsible for the dispensing management of each dispensary.

I recently attended a meeting with Fred Mayer, RPh, president of Pharmacists Planning Service, Inc. He and I met with Stephen Woods, chief of the Food and Drug and Radiation Safety division, and Asif Maan, PhD, chief of the Office of Medical Cannabis Safety of the California Department of Public Health. (Mayer is a member of the Editorial Advisory Board of Drug Topics.)

An Open Letter to the California State Board of Pharmacy

“First and foremost, a pharmacist must be available and partially responsible for the dispensing management of each dispensary.”

I believe that the California State Board of Pharmacy should begin creating the new rules for this as an upcoming area of our profession.

I would like CPhA to be at the forefront of this new exciting opportunity for the profession of pharmacy.
Know the Top 8 Violations for Controlled Substances

Controllable substances can be a minefield. Despite articles, seminars, and opinions written on compliance and the legal implications of dispensing, ordering, and storing controlled substances, it remains the number one reason for disciplinary actions. Here are the most cited violations of state or federal laws pertaining to controlled substances.

▶ Improperly performed inventories. Pharmacy inventory commonly omits time of day the inventory was taken or the finished form of the substance. Many states have modified their requirements on proper inventory. California, for example, now requires a manual count of all Schedule II drugs at least every three months.

▶ Records of receipt and dispensing. Dispensing records must state number of units dispensed, name and address of the person to whom it was dispensed, date of dispensing, and name or initials of the person who dispensed. Pharmacy records often omit patient addresses, the DEA number of the prescriber, or include entry errors. Invoices and ordering records must be properly prepared and have information on the supplier, date of receipt, and number of containers.

▶ Power of attorney. All ordering personnel must properly execute a power of attorney with the registrant. Often, the power of attorney is not dated, does not come from the registrant, or is missing.

▶ Physical controls. It is recommended that all Schedule II drugs be locked, and Schedules III-V be separated from the rest of the inventory and be in a high-visibility place (not at the back of storage or by the bathroom). The keys to the controls should be in the possession of a pharmacist at all times.

▶ Employee screening. Federal regulations say a pharmacy shall not employ anyone with access to controls who has been convicted of a felony relating to controls or whose application with the DEA had been denied, revoked, or surrendered for cause. Pharmacies should run state, county, and federal background checks on all employees with access to controls.

▶ Reporting theft/loss. Pharmacy must report any theft or substantial loss of controls within one day of discovery by filing Form 106. If the filing is not timely, the DEA may investigate the delay. It is common to delay filing Form 106 while the investigation is pending. However, the DEA requires that the registrant file the report first and then investigate. If the pharmacy determines there was no loss or no significant loss, the report may be withdrawn or amended. States vary on reporting requirements.

▶ Security features on prescriptions. Many states have updated their requirements on what information should be stated on a prescription. California now requires a new security feature, a serial number uniquely attributable to a prescriber. If a prescription for Schedule III-V medications is missing any security features, a pharmacist may treat a noncompliant form as an oral prescription. The pharmacist must verify the order with the prescriber and include notations on the prescription form.

▶ Corresponding responsibility. Pharmacists can run into this problem when they do not run PDMP reports on new and existing patients or are filling scripts coming from problematic prescribers who are already on the DEA’s or medical board’s radar. Every record-keeping violation could turn into a monetary penalty. Train your staff on proper record-keeping, follow every state and federal regulation, and incorporate them into your policies and procedures. These steps are part of complying with state and federal regulations on dispensing and handling controls to avoid possible disciplinary or DEA actions, and penalties.
Provider and Payment Status: An Update

More than 100 provider status bills pending in 34 states, but national remedy uncertain  By Fred Gebhart, contributing writer

Do you want to be recognized as a healthcare provider? Or do you want to get paid for the clinical services you provide? It’s a trick question that has brought years of confusion as pharmacy fights to achieve provider status.

“At the federal level, ‘provider status’ describes access to Medicare Part B,” says Krystalyn K. Weaver, PharmD, vice president of policy for the National Alliance of State Pharmacy Associations. “Provider status is shorthand for ensuring that patients can get access to the clinical services that pharmacists provide and that pharmacists get reimbursed for providing those services. It’s a different story at the state level.”

Pharmacists are already classified as providers in most states, Weaver says. But what that means depends on just where in state law pharmacists are classified as providers. It depends on pharmacists’ scope of practice under state law. And most importantly, it also depends on what states do or do not require in terms of reimbursement for pharmacist services.

Many states are silent on reimbursement. Other states require pharmacists to be paid for services provided under state employee health plans or Medicaid.

For example, the Washington state legislature dramatically expanded pharmacist scope of practice in 1979, allowing for collaborative practice agreements (CPAs) across a broad range of activities. There are currently more than 33,000 active CPAs across Washington in prevention, wellness, immunizations, disease state management, opioid management, HIV pre-exposure prophylaxis, and other areas.

“What we found is that while we were able to provide the care, we were not necessarily able to be paid for care under either the medical benefit or the pharmacy benefit in commercial health plans,” says Jeff Rochon, PharmD, CEO of the Washington State Pharmacists Association (WSPA).

“If, in fact, the services a pharmacist is providing are going to benefit the medical side of the equation, then there should be claims under the medical benefit. That’s the real provider status conversation.”

The WSPA worked with the state legislature to require private insurers to include pharmacists in provider networks in 2015.

If a medical service is covered when provided by a physician, nurse practitioner, or other traditional provider, it must also be covered if provided by a pharmacist, as long as the service is within the pharmacy scope of practice.

Billing Solutions Needed

WSPA’s legislative win in 2015 was only the first step in getting paid. The real barrier was figuring out the mechanics of submitting successful medical claims.

“Once we had the legal side, we had to learn how other providers do things,” Rochon says. “There was quite a bit of knowledge to be gained in understanding credentialing and contracting, and enrollment in health plans as individual pharmacist providers. There was understanding how to submit a medical claim, who to submit it to, the whole language and practice of ICD 10 and CPT codes, and documentation.

“There is the IT side, how do we communicate, not only with the health..."
plan, but with other providers so there is continuity of care? And there is the outcomes side, showing that pharmacists are meeting the same quality measures that doctors and hospitals and clinics are held to. The thumbnail is that we have had to learn how other providers bill claims for medical services and meet the same provider obligations as physicians, nurse practitioners, and everyone else in the medical system.

Ambulatory care pharmacists are routinely paid for services, Rochon reported. Pharmacists were already managing patients for opioid use, anticoagulation, behavioral health, oncology, and other areas. Health systems have an existing support system to help other providers in billing that pharmacists could use.

Pharmacists in primary care are also billing successfully for office visits. Community pharmacy has been slower to bill because there was no preexisting mechanism for medical claims in prescription dispensing software. Now, more community pharmacies bill medical claims as more IT solutions come to market.

**Entrepreneurs Needed**

North Carolina went another route. The state gives pharmacists broad leeway to practice under clinical services agreements with physicians, but is silent on payment. That hasn’t stopped Olivia Bentley, PharmD, and other North Carolina pharmacists from actively managing patient care and getting paid for their services.

She is one of more than a dozen clinical pharmacists at Rx Clinic Pharmacy in Charlotte who spend 100% of their time in direct patient care.

“It is all about entrepreneurship,” Bentley says. “Sometimes a practice leases pharmacist services by the hour or the day. It can be anything from prior authorizations to dealing with questions from dispensing pharmacists, coordinating care, managing therapy, anything medication related.”

“Other times it is a fee-for-service model where we bill for the practice and share financial risk. That means you learn the ins and outs of billing and coding for medical claims,” she says. “There are shared revenue arrangements where we keep a percentage of the gross revenues we bill and bring in. And there are more familiar services—diabetes education, DME, insulin pump training—a host of clinical services provided by pharmacists and billed by pharmacists. Being able to bill third-party payers directly for all of our services would be nice, but it’s really about working at the top of your license and getting creative with business models to get paid for it.”

Washington is the model in terms of payment for services, Weaver says. But Idaho is the model for scope of practice. Idaho will now allow pharmacists to prescribe for anything that does not require a diagnosis, a broad swath of preventive services, and any condition that has already been diagnosed.

“Once the law is implemented, a physician could write a diagnosis on a prescription pad and a pharmacist could manage the patient’s therapy based on that diagnosis,” she says.

**Moving on Multiple Levels**

There are more than 100 provider status bills pending in 34 states for 2019, Weaver says. On the federal level, a provider status bill introduced in the last Congress had more than half of both houses as co-sponsors, but the bill still foundered. A new bill will likely be introduced before the summer recess, says Alicia Kerry J. Mica, senior lobbyist for APhA. The new legislation will likely focus on pharmacist services in reducing opioid misuse in medically underserved areas.

“APhA is part of a larger effort, the Patient Access to Pharmacists’ Care Coalition, with health system pharmacists, community pharmacists, chain pharmacists, and other groups,” she says. “We are not trying to be the sole point of care, we are there in areas where there are no other providers. In areas that don’t have a lot of physicians, pharmacist access means a lot.”

Pharmacist access also means a lot in areas with plenty of providers. Washington may have the broadest access to pharmacist reimbursement for services, but WSPA is still pushing for federal provider status.

“Until we get federal provider status, patients that have Medicare don’t have the same access to pharmacists as other patients,” Rochon says. “We have to have federal provider status as well as state-level changes if we are going to be able to provide care to all our patients.”

**OLIVIA BENTLEY, PHARMD**
Erythroid Maturation Needs to Stay on Track

Impaired maturation contributes to ineffective erythropoiesis, which can lead to chronic anemia$^{1,2}$

- Ineffective erythropoiesis may be characterized by increased proliferation of erythroblasts, increased erythroid cell death, and impaired erythroid maturation, which may result in chronic anemia$^{3,4}$

- Chronic anemia can have long-term consequences for patients with various blood disorders, such as myelodysplastic syndromes (MDS), β-thalassemia, myelofibrosis, and Diamond-Blackfan anemia$^{5-8}$

Research is expanding what we know.

**References:**


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Training Technicians for More Responsibility

As numbers and complexity of medications grow, so will the need for training

By Ken Krizner, contributing writer

Product-wise, they are worlds apart. Yet, a common bond exists between fast-food restaurants and pharmacies. Both businesses are expected to place a premium on customer service. For that reason—as surprising as it might sound—when Eric Shoffner, BPharm, PD, and owner of iCare RX in Newport, AR, is seeking prospective new pharmacy technicians, he sees fast-food restaurants as fertile ground for his search.

“There is always someone in the restaurant running around like a chicken with its head cut off,” Shoffner says. “Those employees are doing more than anyone else. They’re the individuals I target. I ask them to consider a healthcare occupation.”

Not everyone jumps at the opportunity. Shoffner estimates that three or four out of 10 fast-food employees show interest when approached. But if employees show potential in the fast-food environment, they stand a better chance of succeeding as a pharmacy technician, he says.

Once a person who shows potential is found, technician training is an absolute must. As pharmacies have evolved, so has technician training. With pharmacists doing more patient counseling than ever before, it is up to the technician to make sure the pharmacy itself is running efficiently and safely.

“My pharmacy is clinically oriented, and our pharmacists are practitioners,” says Dennis Song, RPh, owner of Flower Mound Pharmacy in Flower Mound, TX. “I shift a lot of the day-to-day responsibilities to my technicians.”

Not only do technicians need to know the “soft skills” of customer service, they need to be proficient in data entry and possess clinical aptitude—the “hard skills” of the job, Song says.

“Technicians need to be ‘technical’ because there is so much to work through in terms of prior authorizations, insurance rejections, and other issues,” he points out. “There is no manual, so a technician has to be able to think through these issues and come up with solutions. Critical-thinking and problem-solving skills are a must.”

The Need for Training

Training is growing in importance because there is expected to be an increase in the need for technicians. According to the Bureau of Labor Statistics, nearly 450,000 pharmacy technicians will be needed in the United States by 2026.
The Growing Role of the Technician

Pharmacy technicians are assuming more of the day-to-day responsibilities behind the counter, allowing pharmacists to remove themselves from those tasks and concentrate more on high-quality patient counseling and care.

Responsibilities of a technician can include:

- Data entry
- Administrative duties
- Workforce scheduling to meet the demands of the pharmacy
- Sterile and nonsterile compounding
- Filling and counting

In some states, technicians can provide immunizations and assist in vaccine administration.

In health systems, the role of the technician can include inventory management, drug diversion, medication reconciliation and retrieval.

Source: DrugTopics research

Training also reflects the broader changes in pharmacy. As pharmacists provide more patients with more clinical services, such as medication therapy, immunizations, medication reconciliation, and health screenings, technicians will shoulder a larger burden of the workflow.

"Even as we move toward the pharmacy becoming more of a primary healthcare destination, the traditional tasks will still continue," says Jeremy Sasser, pharmacy content strategist for National Healthcareer Association (NHA). "Pharmacy technicians fill that void while pharmacists carry out clinical duties."

There are numerous educational and training programs for pharmacy technicians throughout the country, offered by colleges and universities, high schools, technical and vocational schools, allied health programs, career institutes, and training centers, as well as some sponsored by corporations and health systems.

The expansion of the role of the technician prompted the Pharmacy Technician Certification Board (PTCB) to change its eligibility requirements for the Certified Pharmacy Technician (CPhT) Program and update its Pharmacy Technician Certification Exam (PTCE). Beginning in 2020, PTCB will offer two eligibility pathways for technicians submitting certification applications—completion of a PTCB-recognized education/training program or equivalent work experience.

"Technicians are an integral part of the pharmacy team," says David R. Bright, PharmD, BCACP, immediate past president of PTCB’s Certification Council and associate professor in the Department of Pharmaceutical Sciences at Ferris State University’s College of Pharmacy in Big Rapids, MI. "We believe the time is right to recognize and support the level of preparation that has become more standard in the field to advance medication safety and patient care."

Students who complete a PTCB-recognized education/training program will be eligible to apply for and earn their CPhT credential. PTCB’s work experience alternative is for technicians who have completed 500 work hours and can attest to fulfilling specified knowledge requirements.

Aside from new eligibility requirements, PTCB recently granted more than 500 Compounded Sterile Preparation Technician (CSPT) certifications, the organization’s first advanced certification program, which was launched in December 2017.

"Sterile compounding requires advanced knowledge, close attention, and skill proficiency to ensure patient safety," Bright stresses. "This credential allows a pharmacy technician to mark his or her accomplishment and expertise in sterile compounding in a consistent way across the profession."

Once technicians are trained and working in the pharmacy, continuing education (CE) is a necessity to keep current with medication safety, new classes of medications, workplace performance and other responsibilities, explains Liza Chapman, PharmD, FAPhA, vice president of partnership development for PTCB. The organization requires technicians to take 20 hours of CE every two years to maintain national certification. One of the required hours is on medication safety and another hour is on pharmacy law.

In addition to the CPhT and CSPT accreditations, PTCB recently announced the addition of five assessment-based certificate programs for advanced technician roles, and an Advanced Certified Pharmacy Technician (CPhT-Adv) credential.

"My pharmacy is clinically oriented, and our pharmacists are practitioners. I shift a lot of the day-to-day responsibilities to my technicians."

DENNIS SONG, RPH

The five certificate programs under development are Technician Product Verification (Tech-Check-Tech), Medication History, Controlled Substance Diversion Prevention, Billing and Reimbursement, and Hazardous Drug Management. Candidates seeking to be a CPhT-Adv will be required to have earned at least four of the new certificates to be eligible.

Growing Responsibilities

PTCB’s program changes are based on
data collected via a job task analysis survey of more than 40,000 respondents, as well as comments from technician employers, educators, state and national pharmacy associations, and state boards of pharmacy.

The changes stemmed from input received at the 2017 Stakeholders Consensus Conference. That conference was instrumental because the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE) revised their national standards for pharmacy technician education and training.

The standards became effective for new programs at the beginning of 2019. Existing accredited pharmacy technician programs will be required to incorporate the new standards by Jan. 1, 2020.

The revised standards place additional emphasis on the educational outcomes expected of students and the methods used by training programs to assess competency. Competencies are defined to differentiate entry-level and advanced-level training, structural and process-related elements needed for program quality, and evidence-based outcome measures.

The number of standards has increased from six to 15. Each standard highlights the key elements that must be met to demonstrate compliance. The key elements model those in pharmacist education and training programs and emphasize collaboration with pharmacists and other healthcare personnel.

The reassessment was prompted by several factors, including changes in state laws that allow for expanded technician roles, responsibilities, and authority, says Lisa Lifshin, BSPharm, director of program service for ASHP.

“The preparation of medications is more extensive than ever before,” she notes. “There are more high-risk and dangerous medications to prepare—more than just a few years ago. Plus, new drugs are introduced all the time. The more technicians can be educated, the better.”

“[Technicians] are an absolute necessity in all facets of the profession.

As pharmacists, we can’t do what we do every day without technicians.”

LIZA CHAPMAN, PHARMD, FAPHA

NHAs new training product, PharmaSeer, exceeds ASHP’s revised standards. Sasser describes the product as a comprehensive approach to teaching individuals everything they need to know to practice as a technician. NHA markets its product primarily to employers and academic institutions such as community colleges and vocational programs.

“We’re trying to take into account the marriage between didactic training and applying what is learned to hands-on tasks that go on behind the counter,” Sasser says. “We want to provide technicians with a baseline knowledge, so they can have confidence in the skills needed for the role.”

The Modern Pharmacy

At a time when margins are tight, many pharmacies are transforming into patient-centered enterprises, where the pharmacist interacts with customers on a regular basis, almost assuming the role of primary care physician.

In this environment, pharmacists remove themselves from the daily grind of filling prescriptions and fulfilling administrative tasks. Those responsibilities fall on the shoulders of a well-trained technician staff.

At Flower Mound Pharmacy, pharmacists cannot enter data, adjudicate and fill prescriptions electronically, count, or manage inventory. “I don’t want my pharmacists to perform [those responsibilities],” Song maintains. “Pharmacists are there to address specific patient needs.

“To be patient-centric, it is critical that pharmacists have confidence in the ability of their technicians,” he stresses.

“The modern pharmacy must operate with competent and forward-thinking technicians, especially when quality measures, outcomes, and value-based medicine are taken into consideration.”

iCare RX’s Shoffner says at one time, the role of the technician was simply to watch the pharmacist do the work. Today, pharmacists perform their responsibilities and technicians do everything else.

With a population that continues to age and life expectancies continue to increase, the number of medications prescribed will continue to grow, and with it, more comorbidities. More high-quality counseling will be necessary to help patients avoid adverse outcomes.

“Pharmacists will be more involved as a provider, delivering more information to the patient,” ASHP’s Lifshin says. “We will continue to see technicians taking more responsibilities so pharmacists can provide that type of patient care.”

As a former community pharmacist, PTCB’s Chapman stresses she could not have met the demands of everyday work without the assistance of trained technicians.

“They’re an absolute necessity in all facets of the profession,” she points out. “As pharmacists, we can’t do what we do every day without technicians.”

Which is why technician training and education is so vital for public health, job stability, professional advancement and consistency throughout the industry.
Summer is here, and the time is right to buy and apply sunscreens, or at least it is the time when most Americans think about sunscreens. But deciding when, where, how much, and what kind of sunscreen to apply has become complicated.

The bottom line remains the same: using sunscreens can help prevent sunburn and skin damage, and reduce the risk of developing skin cancer. But new research on the systemic absorption and effects of sunscreen ingredients, as well as ecological effects, is making what used to be a relatively simple choice more difficult. Here is why.

Sunscreens are formulated to work on the surface of the skin. It had previously been thought that sunscreens would not be absorbed systemically in appreciable quantities; however, a study published May 6, 2019 in *JAMA*, confirmed that ingredients in sunscreens are absorbed in the bloodstream. Researchers looked at four active ingredients (avobenzone, oxybenzone, octocrylene, and ecamsule) in commercially available sunscreens. Application of these four sunscreens under maximal use conditions resulted in plasma concentrations that exceeded thresholds established by the FDA. These new findings raise concerns that high levels of sunscreen ingredients in the bloodstream may lead to hormonal and other changes.

Consumers should be applying sunscreen several times a day across large portions of their body when they are out in the sun. Ingredients from sunscreens have been found in blood, urine, and breast milk. There has always been a concern that individuals may inadvertently inhale sunscreen when spraying it on, or ingest some when applying products to their lips, potentially harming the lungs or internal organs.

The FDA is taking a closer look at sunscreen ingredients. In February, the agency issued a proposed rule that would update regulatory requirements for most sunscreen products in the United States. The new rule would address active ingredient safety, dosage forms, sun protection factor (SPF), and broad-spectrum requirements. It also proposes updates to product labeling.

The FDA is currently seeking public comment on the proposed rule, which will address dosage safety on sprays, oils, lotions, creams, gels, butters, pastes, ointments, sticks, and powders. It is proposing that sunscreen wipes, towelettes, body washes, shampoos, and other dosage forms be categorized as new drugs because of a lack of safety data. The agency is also raising the maximum proposed SPF value on sunscreen labels from SPF 50+ to SPF 60+.

In November 2018, Zambrana and colleagues presented new data at the American Association of Pharmaceutical Scientists PharmSci 360 Meeting showing that heat and reapplications may influence the safety and toxicity of the UV filters in sunscreens. The findings suggest that current safety testing procedures may be underestimating the amount of oxybenzone being absorbed into the skin by someone sunbathing on a beach.

Companies commonly add a form of vitamin A to sunscreens and moisturizers with SPF. Vitamin A may help contribute to skin tumors and lesions when used on skin in the presence of sunlight.

Marie Perucci-Bailey, PharmD, quality and operations supervisor with the University of Virginia Health System Ambulatory Pharmacy Services in Charlottesville, says there is no current reason to recommend against the use of vitamin A in sunscreens or other skin products. "However, if a patient is concerned and would prefer a sunscreen product that does not contain a form of vitamin A, I would recommend a chemical barrier..."
CLINICAL PRACTICE

sunscreen, such as zinc oxide or titanium oxide," she says.

"I am not concerned about vitamin A penetration," says Alice C. Ceacareanu, PharmD, PhD, professor of translational biomedical research management at Hartwick College, Oneonta, NY. "I am more concerned about lack of vitamin D production due to sunscreen use. Vitamin D is an anti-inflammatory molecule that protects against cancer and diabetes, and of course, osteoporosis as well. Nonetheless, taking vitamin D is an option. Not applying sunscreen has far bigger consequences," she says.

Currently, several groups of investigators are looking at whether ingredients in sunscreens may adversely affect hormonal levels, including testosterone levels in adolescent boys. Other studies have raised red flags about oxybenzone exposure during pregnancy. Perucci-Bailey does not think that the hormonal effects of sunscreens are a significant concern and that pregnant women should be advised to use sunscreens appropriately.

"There is no evidence to support avoidance of sunscreens while pregnant," she says. If a woman is concerned and wants to avoid use of sunscreens with oxybenzone, she would recommend a barrier sunscreen.

To complicate the subject of sunscreens further, some ingredients in sunscreens may be harmful to marine life. Researchers found octocrylene, which is also in some cosmetics and hair products, may build up in coral and become toxic to marine organisms. Studies have shown that sunscreen ingredients shed by swimmers can contribute to coral reef decline. The state of Hawaii has banned sunscreens containing oxybenzone and octinoxate, two chemicals known to harm coral. The law takes effect in January 2021.

**Sunscreens and Skin Cancers**

There is overwhelming evidence that sunscreen prevents or limits sunburn, which is what causes skin cancer. Although there is no proof that sunscreens prevent all types of skin cancers, sunscreens are still the best-known prevention. "Sunscreens are always recommended when people are going to be exposed to intense ultraviolet rays. Experts recommend that the highest possible SPF values be used to avoid painful sunburns that can cause various types of skin damage and lead to skin cancers, including basal cell, squamous cell, and melanoma," Dwight Kloth, PharmD, director of pharmacy at Fox Chase Cancer Center, Philadelphia, PA tells Drug Topics. "Children are especially susceptible and have the greatest number of years to experience the negative sequelae from a severe sunburn."

Blake Phillips, MD, a dermatologist at University of Alabama at Birmingham, says there are many studies that show a protective benefit from sunscreen use for melanoma and nonmelanoma skin cancers. "There are not overwhelming numbers of large-scale long-term randomized trials, largely because running these trials would be considered unethical," Phillips tells Drug Topics. Sunscreens effectively protect against UV exposure. Phillips says. The majority of skin cancers arise from exposure to UV radiation which tends to be chronic, accumulating over decades. "There is a wealth of human safety data for sunscreens," says Phillips.

Phillips says he believes pharmacists play a key role in advising patients about skin cancer prevention. They can effectively counsel patients about which medications they may be taking that are photosensitizing, "I encourage patients to choose a sunscreen that they will actually use."

Pharmacists also can help patients review all their drug regimens and identify any agents that may increase skin cancer risk, such as immunosuppressive medications, voriconazole, and other agents, Phillips notes. "I tend to direct children and those with sensitive skin towards the physical-blocking sunscreens."

Kloth says, "Pharmacists can also reinforce proper techniques for using sunscreens."
Discount Drug Cards 
Flourish with End of Gag Rule

Programs increasingly cater to the uninsured and underinsured

By Mari Edlin, contributing writer

Discount drug cards appear to be the product du jour in healthcare, from those marketed by pharmacy benefit managers (PBMs) and retailers to those from drug manufacturers and membership organizations, such as AARP.

The main motivation behind more cards and agreements to increase patient savings is the revocation of gag clauses that censored what pharmacists could tell their patients.

Some cards have a track record, while others have just entered the market. FamilyWize has been around since 2005. NeedyMeds has offered a discount card since 2009, GoodRx since 2015, and Express Scripts’ Inside Rx since 2018. Many cards have an app that offers information and help to users.

Last December, CVS Caremark partnered with Sharecare, an Atlanta-based digital health company, to launch a digital pharmacy savings card targeting the uninsured, the underinsured, and those with a high deductible. The PBM administers the program and provides medications through 68,000 pharmacies in its network.

Some skeptics question whether these cards really save customers money, but those who offer them are confident about their value, transparency, and ability to improve adherence—an important issue. According to a Kaiser Family Foundation survey, among those currently taking prescription drugs, 24% of all adults and 23% of seniors say it is "difficult" to afford their prescription drugs, including about one in 10 (overall and among seniors) who said it is “very difficult.”

In 2017, the Annals of Internal Medicine estimated that a lack of adherence causes nearly 125,000 deaths and 10% of hospitalizations a year, while potentially costing the healthcare system as much as $289 billion a year. As many as one-third of prescriptions are never filled.

Aiding Adherence

Livea Byrne, vice president for product communications for Sharecare, says the company’s new card is part of a larger product vision that offers tools and features to overcome adherence barriers. “The first fill is the most important in terms of helping patients remain compliant,” she says.
**PHARMACY PRACTICE**

"Our strategy follows a completely different model than traditional discount drug cards by including our consumer platform, which also provides content, education, safety, and messaging to address the most prevalent barriers to adherence and compliance."  

**HOWARD GRUVERMAN**

Ken Majkowski, PharmD, chief pharmacy officer for FamilyWize, based in Bethlehem, PA, agrees with Byrne. “The impact of a discount card is on first fill. If consumers don’t get a discount, they might not fill their prescriptions, affecting adherence. However, it is difficult to measure the effect of a card on adherence,” he says.

“Our strategy follows a completely different model than traditional discount drug cards by including our consumer platform, which also provides content, education, safety, and messaging to address the most prevalent barriers to adherence and compliance,” says Howard Gruverman, executive vice president of enterprise at Sharecare. “It will be important to study and validate the impact cards make in improving adherence across populations.”

One of the primary features of the Sharecare Rx card is the Discover section on the Sharecare app that includes helpful search features for members, including medication prices, finding a doctor, and other tools.

With the app, users may opt to get notifications and reminders to refill their prescriptions, as well as information on how to take their medications as directed; drug-specific information on safety and side effects; alerts about interactions; and can track their medications.

Cardholders can create a profile on Sharecare’s stand-alone platform so that all data reside in one place. “Patients’ medical information typically lives in many different systems so that having a complete list of medications ensures members have easy and convenient access to the information no matter where they are,” Byrne says. Cardholders also may search for a specific medication, filtering results by price, pharmacy location and hours, and availability.

The company is working with its health plan and employer partners to integrate their formulary coverage and pricing into Sharecare, providing seamless access to prescription benefits and information.

Gruverman says users could save up to 80% on generics and take advantage of a wide variety of discounted brands. “This alleviates a major cost burden for people who manage chronic conditions and lack adequate insurance or the resources to purchase these medications,” he says.

The downside is that discount drug card expenses do not count toward a patient’s deductible or out-of-pocket maximums and cannot be combined with insurance; however, some of Gruverman’s peers recommend that consumers submit receipts to their insurers for potential credit.

He sees the development of innovative drug pricing models as more consumers use smartphones and digital tools to manage parts of their everyday lives, and as additional players across the healthcare landscape, such as payers, PBMs, and employers deploy tools to make medications more affordable and accessible.

Headquartered in Gloucester, MA, NeedyMeds, a nonprofit resource helping people afford their medications, has saved consumers $275 million since its card’s inception. The company claims 40,000 transactions take place per month with its card, which covers more than 6,000 drugs.

Richard J. Sagall, MD, president and cofounder of NeedyMeds, says that since the gag rule was lifted last October, which prohibited pharmacists from proactively telling consumers when prescriptions would cost less when paid for out-of-pocket rather than using their insurance plan, discount drug cards offer even more value.

**What’s in it for Pharmacies?**

The financial path all discount cards take could have fees that end up coming out of consumers’ pockets, Sagall has noted on the NeedyMeds blog.

These fees include negotiated discounted price by PBMs, transaction fees by pharmacies each time a card is used, PBM transaction fees to cover costs of setting up and running a pharmacy network and processing claims, and marketer fees that go toward card promotion and distribution.

Sagall questions why pharmacies would accept a drug card when it could seem to be in their best interest to charge customers a nondiscounted price, but he also notes five reasons why they would:

1. They can discount a drug just enough to make some profit.
2. They can sell prescriptions they might otherwise not sell if a customer cannot afford a drug at the regular price, even if the pharmacy earns a lower profit.
3. They can build customer loyalty by offering drug discounts.
4. Peer pressure could prompt a pharmacy to offer a discount card if its competitors do. Buyers should beware when selecting drug discount cards, he notes. They should make sure the card is free, doesn't require registration and input of personal information, offers as much of a discount as other cards, and has a helpline.

**The Savings**
Inside Rx, a pharmacy savings program, boasts $400 million in savings since it was introduced. Leslie Achter, CEO, says the Inside Rx card is the result of partnerships with both manufacturers and retailers.

It offers 150 featured program brands at 40,000 retailers, which cover 35 conditions that accrue 40% discounts. The card saves 80% off generics.

The drugs covered primarily target high-cost chronic conditions and, of late, more lifestyle drugs such as erectile dysfunction medications and female products for menopausal symptoms, Achter says.

“We serve those with insurance, those under-insured and uninsured,” she says. “The card is helpful for those under a high-deductible plan and for the insured when their plans don’t provide coverage for a certain medication.

“With more consumer demand for information, the card enables users to see the real price of a drug online and its varying costs at different pharmacies,” she says.

The largest downside is not being able to use a discount drug card in government programs such as Medicare, she says.

GoodRx has had a good run since the card’s launch in 2015—$9 billion in savings and 10 million users at 70,000 pharmacies.

Tori Marsh, health insights analyst for GoodRx, says the company got off the ground when co-CEO Doug Hirsch tried to fill an expensive prescription and found varying prices at different pharmacies. He recognized the need for a one-stop destination for prescription discounts and prices.

Agreeing with Achter, Marsh says, “Cards are a way to shop around as prices continue to grow, eliminate reliance on insurance, or cover drugs no longer on a member’s formulary. Consumers are on the hook for more cost sharing than ever before.”

GoodRx covers all FDA-approved drugs, including biologics (even if there is only one manufacturer) and over-the-counter medications, and provides a 15% to 20% discount for brands and 80% for generics. It works with everyone in the pharmacy chain to ensure all of its prices are up to date and accurate.

The company also offers GoodRx Gold, a monthly membership program that provides significant discounts on prescription drug and healthcare services. The cost is $5.99 per month for individuals and $9.99 per month for a family of up to five members and it provides more than 1,000 prescriptions for under $10.

**Positive Perception Grows**
“Public perception of drug discount cards was low, but the end of the pharmacist gag rule has brought them to the forefront,” says FamilyWize’s Majkowski.

“‘There is more awareness by providers and patients about drug price transparency,’ he says.

Like many of its competitors, FamilyWize offers a digital card, in which consumers can input pharmacies and receive alerts to use the card.

Majkowski estimates that about 10% to 15% of drugs are purchased via a discount card or coupon.

The FamilyWize card offers 45% discounts off multisource generics, with a lower discount for single-source generics and brands.

FamilyWize has saved 13 million people $1.5 billion since its inception in 2005, enabling users to purchase drugs at 60,000 chain and independent pharmacies.

Majkowski touts the benefits of discount cards by emphasizing that there are no eligibility requirements; users can be uninsured, insured, or underinsured; do not have to be a U.S. citizen; and even can apply discounts to purchases made by relatives.

On the other hand, Majkowski says some of the independent pharmacies do not always share the same enthusiasm about cards as consumers because their customers would pay more of the usual and customary prices without the card.

FamilyWize passes along 100% of discounts to consumers, while other vendors might use rebates or keep some of the discount as part of their spread.

Majkowski sees a trend toward pharmacies relying on discount cards from third parties rather than sponsor their own because they don’t want to risk running afoul of Medicare and Medicaid laws.
10 Methods that Will Boost Your Customer Loyalty

Services, activism, and product offerings will attract new customers and keep current ones coming back.

By Keith Loria, contributing writer

With today’s increasingly crowded pharmacy landscape, patients have more places to choose from to fill a prescription or shop than ever before, so it’s important for every pharmacy to set itself apart and offer a reason for people to come back time and again.

“Consumer trends, especially related to retail, are changing rapidly, and patients are going through a fundamental shift in their values, seeking a more personalized healthcare experience,” says Claire Biermaas, group vice president, strategic accounts at AmeriSourceBergen, in Chesterbrook, PA. “Retail pharmacies that can address these changes will best position themselves to strengthen loyalty and improve in-store experiences with their customers, increasing repeat visits, script counts and business.”

Fernando Gonzalez, RPh, spent years as a pharmacy development manager for Rite Aid, Duane Reade, and CVS, where he learned to recognize that it is six to seven times more expensive to search for a new customer than keep an old one. He is currently assistant professor in the Pharmaceutical Sciences Division at Long Island University’s Arnold and Marie Schwartz College of Pharmacy and Health Sciences.

“The key starts with having the pharmacist create a connection with the patient that involves trust and individual service,” he says. “Trust starts with knowing your patients and customers and showing them your expertise.”

Keep in mind that a loyal customer will share his or her feelings with others and a positive word of mouth will have a tremendous impact on a business.

Here are 10 things a pharmacy should be doing to improve customer loyalty.

1. Be Personable

Kristi C. Torres, PharmD, pharmacist-in-charge at the Austin Diagnostic Clinic Pharmacy in Austin, TX, says pharmacists sometimes get so busy that they become almost automated.

“It’s so important to slow down and really listen to your patients,” she says. “They’ll often share quite a bit, both about health and personal issues. Make it a point to ask them about those things again later. When patients feel like you’re listening and paying attention to them, they feel a sense of loyalty to you as a health practitioner and a business.”

Keep your entire pharmacy staff engaged around the level of personal service you expect for your patients to receive. One staff member who is not on board with providing this level of service can drive away many patients. Provide positive reinforcement for the staff who meet this expectation, and quickly correct and reset expectations for any who fall short of exceptional service.

Torres has also had success improving loyalty by going that extra mile to do the little things, such as mailing or delivering prescriptions to those who can’t get to the pharmacy.

“I also let them know when I am aware of available savings on a prescription, such as through manufacturer rebate or copay programs,” she says. “When patients feel like you’re looking out for them as individuals, they feel a sense of loyalty to you and will continue choosing you as their pharmacist.”

2. Start a Conversation

Biermaas says one of the most effective ways a retail pharmacist can drive loyalty is by stepping out from behind the counter to speak with patients.

“Many customers are visiting to add OTC products to their basket, which is an opportune time to start engagement,” she says. “When shoppers see a pharmacist in their white coat out in the store, they feel more comfortable asking questions and seeking out help.”

These interactions can help create a meaningful relationship with patients, and make a big impact on customer loyalty.
experience. They also encourage customers to visit the pharmacy in the future, and can give a boost to frontend sales.”

3. **Use Technology**

Michael Morgan, CEO of Updox, a healthcare technology company in Dublin, OH, says offering two-way text messaging and video connectivity with patients are among the best ways pharmacies can differentiate themselves and build loyalty with patients.

“In rural areas, where the closest pharmacy might be a 30-minute drive or more, pharmacists can counsel elderly patients on their medication use without them having to get their family to drive them to the store and wait in line,” he says.

“Similarly, for homebound patients, pharmacies can offer diabetes education or weight loss counseling via live video.”

These tech solutions can help pharmacies cut down on manual phone calls for refills, insurance card information, and other daily tasks, as well as expand their clinical and patient counseling services.

“Providers who are engaging patients online and using technology to offer flexibility, while also keeping the human touch, have the best opportunity to forge lasting consumer relationships and improve patient loyalty,” Morgan says.

4. **Pay Attention to the Patient**

Saad Dinno, RPh, co-owner of three independent pharmacies (Acton Pharmacy, Keyes Drug, and West Concord Pharmacy) in Massachusetts, says it’s important to focus on the patients and the relationships, and really listen to what they are saying.

That’s why Dinno makes it a point to ask questions about them, their spouse, their family, and to congratulate them and their kids when they have an athletic accomplishment or come home from a good semester at college.

“We strive every day to build foundations of trust and be an essential part of a patient’s healthcare team,” he says. “Studies show that on average, we see patients 35 times a year, meaning we get to chat with them more often than perhaps other practitioners. The chatter could be as simple as ‘How are you?’ or ‘How was your vacation?’ Or it could be sitting down and going through a medication list to ensure they understand their medications and how to take them.”

5. **Maintain Efficient Inventory**

A savvy pharmacy will work with area providers to understand their practices, and their prescribing habits. Make sure to maintain sufficient stock of the most commonly prescribed or recommended items.

“Maintaining an efficient inventory is one of the most important business practices in a retail pharmacy,” Torres says. You win or lose customers by stocking the right products at the right time.

6. **Provide Timely Reminders**

Pharmacists should be looking several months out for timely events where patients may need support.

“For instance, reminding patients that National Diabetes Awareness Month is in November and that the pharmacy offers nutrition services can demonstrate the value a retail pharmacy offers,” Biermaas says. “It also shows patients that their pharmacist is thinking proactively about their health and encourages patients to engage with the pharmacy through multiple channels—adding ‘stickiness’ to their relationship.”

7. **Be Active in Your Community**

Sponsoring small events or sports teams, having booths at health fairs, or doing volunteer work are great ways to help patients get to know you and connect your heart for service to your pharmacy business.

8. **Create Value at the Register**

Position items that demonstrate a commitment to “treating the whole patient,” such as tissues, hand sanitizer, and vitamin C near the pharmacy counter. This can illustrate that your pharmacy provides comprehensive care beyond filling prescriptions. It also anticipates ancillary customer needs, creating convenience, and reinforcing the relationship between pharmacist and patient.

9. **Schedule Surge Support**

During the times of the day or week or year that increased traffic is expected, pharmacies should increase the number of experts that are available to work with patients. By having extra staff on hand, wait times and customer frustration will be limited. Anticipate surge events, such as the beginning of the year when health insurance plans change and people need help. Scheduling additional support will build loyalty with customers who know they can receive help in a timely manner.

10. **Carry Products that Appeal to Your Customers**

Sometimes, patients will ask a pharmacy to carry certain products—something especially true in ethnic communities that may look for products that meet their specific needs. You may want to include a Kosher foods section or a section with Latino or Asian products if your customers might be looking for such items.
Statistics from Clinical Studies

Five Things to Know

Be an expert at evaluating clinical studies with some simple tools

By Jennifer Gershman, PharmD, CPh, contributing writer

Evaluating the results of clinical studies can be daunting, but some simple tools can make it a fun experience. I consider drug literature evaluation to be a journey down a somewhat winding road that ultimately leads to a better understanding of a clinical study.

Each study or clinical trial of a drug tells a story, and it is up to us as pharmacists to use our skills just like a detective to critically evaluate and understand the behind-the-scenes statistics. Statistics are tools that evaluate data to provide important study results. Essentially, clinical trials are types of studies that are the basis of the drug approval process, which is a take-home point that I always emphasized when teaching pharmacy students.

Here are five things to know about statistics from clinical studies:

1. **Read Beyond the Abstract**
   The study abstract is like a restaurant menu in that it gives you a taste of the study and includes descriptions of the most important points. However, the abstract does not go into detail about all the statistical methods used in the study. Reading the full study enables you to take an in-depth look at the results and statistical methods.

   Pharmacy conferences can be a great way to get a glimpse at ongoing or completed research projects through poster presentations, which are basically abstracts or summaries of the study’s results. If the researchers who presented the poster or abstract decide to submit their manuscript to a journal for publication, then the information could change from what was presented. A study by Saldanha and colleagues in the journal *Trials* looked at discrepancies between conference abstracts and the later, full publications and found differences in the main outcome results that were reported. The take-home point is to never base clinical decisions on what is in an abstract or poster.

2. **Determine Whether All Results Were Included**
   When evaluating clinical trials, it is always important to see how the data were analyzed.

   Intention-to-treat is considered the gold standard analysis since it accounts for data from all patients who were randomized or initially assigned to treatment groups. Even if some of the patients failed to complete the entire study, their information is still analyzed and reported in the results. Intention-to-treat is designed to mimic what happens in clinical practice. Patients will not always be compliant with their medications or may experience side effects that cause them to discontinue treatment.

   Per-protocol is another type of analysis, but it should be viewed cautiously since it excludes the results of patients who did not adhere to their protocol treatment. If a patient misses one or two doses, their valuable information may never be revealed in the results. This could make the treatment look better than it really is and lead to biased results.

3. **Know the Most Common Types of Statistics**
   It’s important for pharmacists to have a basic understanding of the different types of variables involved in a study in order to determine what types of statistics should be used.

   When it comes to statistics, there are two basic types: descriptive and inferential. Descriptive statistics use data to provide descriptions of a population, which may include the mean (average), median (middle data point), or mode (value occurring most often) calculations. If you are reviewing a study that involves looking at the average number of pharmacists who report adverse drug reactions to the FDA, then this involves descriptive statistics.

   Inferential statistics make inferences and predictions about a patient population based on a sample of data taken from the population. Inferential statistics are important for clinical trials that are evaluating medications in a treatment versus placebo group for the FDA drug approval process.

   When evaluating clinical studies, you should recognize some inferential statistics that are commonly used. Variables are divided into the three main classes: categorical, ordinal, and continuous. Nominal data are also referred to as categorical and includes variables such as sex, presence of disease, and smoking status. Ordinal data involve
rankings, such as if you were rating a movie, restaurant, or hotel. In clinical studies, this may include a pain scale that measures a patient’s pain intensity. Continuous data consist of variables that can be measured and take on any possible value, which may include height, weight, blood glucose, and cholesterol.

Nominal or categorical variables measured from two independent or unrelated samples are usually analyzed using a chi-square test. The chi-square test is used a lot to evaluate baseline characteristics of patients in randomized trials to show there is no significant difference between the groups in terms of age, sex, use of other medications, or other factors.

The Mantel-Haenszel test is generally used to control for any confounding variables between groups that could introduce bias. For example, if a study is evaluating a weight loss medication, it may be difficult to control the diet of the study participants.

Ordinal data are usually evaluated using the Mann-Whitney U and the Wilcoxon rank sum tests.

Continuous data will generally use T tests, analysis of variance, or analysis of covariance to evaluate these data.

The goal of any clinical trial is to determine whether the results are statistically significant, which is usually designated as \( p < 0.05 \). This means that the difference observed between the two treatment groups would occur by chance fewer than five out of 100 times.

As pharmacists, we should also ask the important question of whether the results are clinically significant or applicable to practice. If a study showed that a new antihypertensive medication lowered blood pressure by 3 mm Hg \( (p < 0.05) \), what would you say about its impact on patients? This may not be clinically significant, but we need to see more outcomes data such as whether it decreases the risk of cardiovascular adverse events and mortality.

### 4. Observational Study versus Randomized Controlled Trial

Randomized controlled trials are considered the gold standard type of study to assess the efficacy and safety of medications because they have defined endpoints and a set protocol. Observational studies can provide information about associations, but cannot assess cause and effect. They should be looked at cautiously when it comes to applying the results to the clinical practice setting.

Pharmacists should look for key terms that identify whether a study is observational; terms like cross-sectional, cohort, and retrospective. Many observational studies analyze data from national databases.

### 5. Odds Ratios and Confidence Intervals

Studies generally use the 95% confidence interval (CI), which is the range of values within which the researchers are 95% confident that the true value lies. For example, a study reports that a diabetes medication taken over six months lowered the A1c by 3% with a 95% confidence interval of 1% to 5%. This means that the researchers are 95% confident that anyone who takes the medication, even outside of this study, for six months will have an A1c lowered by 1% to 5%.

This is a great concept to teach pharmacy students during clinical rotations when evaluating studies for a journal club assignment. If the range of the CI includes zero, there is no difference in efficacy between the two treatment groups. This means the results are not statistically significant.

Odds ratios are used to determine risk of an adverse effect in case control studies. An odds ratio of one means there is no difference between groups in regard to adverse effects. An odds ratio greater than one shows an increased risk of adverse effects, while less than one indicates a lower risk.
Maximizing MTM

Improve your counseling skills to make the most of medication therapy management in your community pharmacy

By Tzipora R. Lieder, RPh, contributing writer

As product reimbursement falls and pharmacies must find other sources of income, medication therapy management (MTM) provides opportunities for pharmacists to increase revenue while using their clinical skills to make a difference in patient care.

“I think our value is no longer in the product-based world,” says Timothy W. Cutler, PharmD, BCGP, interim assistant chief, Department of Pharmacy at UC Davis Medical Center in Sacramento and clinical professor of pharmacy at the University of California, San Francisco. “We can’t get away totally from the product, but we have to be able to have the ability and the bandwidth to do the cognitive function that we were trained to do,” he says.

Monetizing Clinical Services
Income streams from MTM include direct reimbursement for comprehensive medication reviews (CMR), targeted medication reviews (TMR), and indirect reimbursement from decreased direct and indirect remuneration (DIR) fees based on improved quality ratings. According to Miriam Mason, PharmD, staff pharmacist at New Utrecht Pharmacy in Brooklyn, NY, the fee is about $60 for CMRs and $10 to $12 for TMRs.

“For a pharmacy with good volume, that can be a significant amount of revenue,” says Nikki J. Scott, PharmD, director of education at Harps Food Stores pharmacies in Springdale, AR.

What impact this will have on a pharmacy’s revenue stream depends on its contracts, Scott says. In pharmacies where DIR fees are assessed at the pharmacy level, effective provision of MTM can significantly impact pharmacy DIR fees in just three to six months, she says, adding up to tens of thousands of dollars quarterly. Pharmacies where
DIR fees are assessed at the pharmacy services administration organization (PSAO) level can encourage improved quality of care across the PSAO, which in turn affects all the pharmacies’ DIR fees.

There are several resources that community pharmacists can use to increase and improve their MTM services. Rachel Stafford, PharmD, assistant professor of pharmacy practice at University of Arkansas for Medical Sciences (UAMS) College of Pharmacy says signing up with MirixaPro and OutcomesMTM is the bare minimum for community pharmacies. These programs allow a pharmacy to be assigned MTM cases from Medicare Part D plans. Pharmacy students on rotation are also a great resource, she says, and can probably accomplish MTM set up in a day. (Cardinal Health, owner of Outcomes, recently acquired Mirixa Corporation and plans on merging the two platforms.)

Stafford notes that when plans assess a pharmacy’s metrics, including adherence to different medication classes, they look at all the patients on the plan, not just those for whom MTM cases are being assigned. Pharmacy ratings also factor in a plan’s decisions whether to continue including a pharmacy in their network. Pharmacists can identify their nonadherent patients and work on improving metrics by using resources like the EquiPP platform and PrescribeWellness, she adds.

**Beyond MTM**

Opportunities for reimbursement for comprehensive medication management (CMM) services outside the framework of Medicare Part D may not come easily, but they do exist. Since becoming an owner at Towncrest Pharmacy, with locations in Iowa City and Solon, IA, in 2006, Randy McDonough, PharmD, BCGP, BCPS has pursued multiple avenues to demonstrate the value of—and be reimbursed for—the continuous medication monitoring (CoMM) he provides. Towncrest stratifies each patient’s risk level based on medication regimen complexity and provides more intense clinical services for higher-risk patients, making about 2,000 clinical interventions monthly, he says.

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**Educational Resources for MTM**

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<th>CE credits</th>
<th>Cost</th>
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<td>APhA</td>
<td>Delivering Medication Therapy Management Services</td>
<td>4 modules self-study</td>
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**Motivational interviewing**

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<td>Bruce A. Berger and William A. Villaume</td>
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<td>Purdue University</td>
<td>Comprehensive Motivational Interviewing Training</td>
<td>6 modules Based on Berger and Villaume’s book</td>
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In a 2013 pilot project with a major payer in Iowa, Towncrest was paid a professional fee to provide comprehensive case management for more than 600 high-risk patients, resulting in a cost reduction to the payer of approximately $300 per member per month. The payer subsequently developed a value-based pharmacy program through which 74 Iowa pharmacies are paid a performance incentive fee if they hit specified metrics, including total cost of care and clinical metrics.

Towncrest is part of an enhanced MTM model in selected regions of the country in which Medicare Part D reimburses for medication safety reviews. Other clinical services have included an expanded immunization program, employee health screenings paid for by local businesses, and case management services paid for by patients and organizations that care for physically and/or mentally disabled adults in group homes.

Stafford suggests that pharmacists interested in producing income streams for clinical services get to know the physicians in their area; find out about the physicians’ patient populations, their most common problems, and what they are being held accountable for. This information can open the door for collaborations where both pharmacists and physicians can benefit from incentive payments for improved quality metrics for their patients, she says.

Every state has a few value-based payment models, Stafford says. She encourages pharmacists to learn the new lingo of MACRA (Medicare Access and CHIP Reauthorization Act of 2015), MIPs (merit-based incentive payment systems), and APMs (alternative payment models) so they can understand how payment is flowing in the healthcare system and how pharmacists can get involved.

McDonough recommends that pharmacists who are looking to extend their clinical services join local community pharmacy enhanced services networks so they can learn from colleagues and access other payment streams. Through his company, Thrive Pharmacy Transformations, he now offers a 30-week course called ‘Make Every Encounter Count,’ which guides pharmacists in transforming their practices.

**Sharpening Clinical and Counseling Skills**

The clinical skills needed to perform MTM are broader than other routine pharmacy interactions. Instead of looking at individual drugs and assessing their interaction with other drugs the patient takes, she explains, pharmacists performing MTM must look at the total picture: the patient, his/her diseases, and how the various drugs in the regimen work together. They must ask: “Is that disease state controlled and, if not, why? Is it because the therapy needs to be optimized, because they’re not adhering to the medication, or both?” She believes that pharmacists, especially recent graduates with PharmD training, already have these skills, but need to practice using them.

Cutler notes that MTM is a more comprehensive approach that requires more follow-through with the prescriber and the patient. Learning to effectively communicate with physicians and phrase recommendations in a way that requires a yes or no answer is key to being able to make meaningful interventions, according to McDonough.

Since MTM requires pharmacists to
become interventionists, McDonough says they must thoroughly understand therapeutics and current clinical guidelines. He endorses residency training and/or board certification in ambulatory care or geriatrics for pharmacists to improve clinical skills.

MTM certificate programs such as those offered by APhA and PowerPak “are really helpful for the didactic knowledge and its application in the individual patient,” says Cutler. He believes that pharmacists improve these skills when they have more opportunities to practice them.

Fraidy N. Maltz, PharmD, BCACP, assistant professor of pharmacy practice at Arnold and Marie Schwartz College of Pharmacy and Health Sciences of Long Island University in Brooklyn, NY, says the training provided by Mirixa and Outcomes is very helpful, and the online platforms include prompts that help pharmacists conduct and document MTMs.

Pharmacists must probe patients to find out important information, says Maltz.

For example, if a patient discontinues a medication, is it because of side effects, cost issues, or because their lab values improved and they no longer need it? Patients’ concerns may be related to health or cultural beliefs or information they’ve heard, Cutler adds. He emphasizes the need to work with the patient to dispel myths and reinforce facts, while recognizing that compromises sometimes must be made.

“We may think that drug A is the cure and the best drug ever, but if the patient says I can’t afford that $50 copay, sometimes we have to modify to drug B,” simply based on a patient’s circumstances in life.

Pharmacists must recognize the importance of social determinants of health in adherence. The Pharmacy Quality Alliance has developed a framework describing structural, financial, and personal barriers that impact patient access to medications, including cost, transportation and insurance. McDonough says he is involved in discussions about how community pharmacists can work with local social services agencies to obtain help for patients with these barriers.

Mason, who provides MTM over the phone, finds that patients are sometimes resistant to accepting MTM services when they are offered. She feels it’s important to use sales techniques to enthusiastically convince patients to speak to the pharmacist. CMM in the pharmacy results in a shift in a patient’s perception as they move from a friendly relationship with his or her community pharmacist to a therapeutic relationship, McDonough says. When a patient recognizes that the pharmacist is working to optimize his or her medication therapy, it creates tremendous patient loyalty, he adds.

Fitting it in the Workflow
Assigned MTM cases that are not completed within a certain time frame disappear from the Mirixa and Outcomes queues and are assigned to a different pharmacy, Maltz says. So how can a pharmacy that fills hundreds of prescriptions daily find time for MTM?

As a pharmacy resident at the University of Arkansas for Medical Sciences and Harps Food Stores in 2015, Nikki Scott developed a workflow model that allows pharmacists to focus on the direct patient care aspect of MTM. The model trains pharmacy technicians to perform all nonclinical MTM tasks, including tracking and billing for patient cases, scheduling CMR appointments, preparing patient folders for the pharmacist, and performing follow-up prescriber communication. After the system was implemented in 35 Harps pharmacies, the pharmacies experienced statistically significant improvement in MTM completion rates, EQuIP scores, and patient adherence to diabetes and hypercholesterolemia drugs, Scott says. Since this system does not require adding any staff hours, all the income generated from clinical services goes to the pharmacy’s bottom line. A training program for the model, called MTM The Future Today, is now offered throughout the country. More than 500 pharmacists and technicians have been trained, she reports.

At Towncrest, pharmacists are available to perform clinical functions because the dispensing process is led by technicians, whom enter orders. They are aided by automated technology, including an automatic pill counter, a pouch packager, and a robot that fills and labels bottles. A new practice model in the state of Iowa permits technicians to check both other technicians and robots, so final prescription verification does not require pharmacists. The role of the pharmacist in the dispensing area is to perform CoMM to identify medication-related problems for each patient, a process that is streamlined because medication synchronization and compliance packaging has been achieved for one-third of their patients. Other pharmacists are available to follow through on time-consuming interventions so that workflow is not interrupted, McDonough says.

The Future of MTM
Cutler believes that, as pharmacy moves toward automation of the dispensing process, pharmacists will have more opportunity to be out in front, counseling and educating patients. Integrated systems that allow retail pharmacists to access patients’ medical records will improve pharmacists’ ability to make sound clinical decisions, he says.

As the healthcare system shifts toward a value-based approach, he predicts payers will soon start to invest in programs that demonstrate decreases in total patient care costs by managing high-risk patients with CMM. “The pharmacist’s role is just going to explode,” he says.
Pharmacies rely on technology for every aspect of their operations: patient profiles, drug utilization reviews, adjudication, dispensing, clinical services, point of sale, inventory management, wi-fi, phone systems, safety and security, alarms, refrigeration temperature monitoring, bookkeeping, payroll. The list can seem endless.

No matter what promises vendors make about automated upkeep and maintenance, technology does not take care of itself. Human intervention keeps pharmacy systems up to date, secure, and running optimally. And human intervention means pharmacist intervention.

“We have to take a role in technology upkeep,” says Eric Bandy, RPh, owner of Bandy’s Pharmacy and Medical Equipment in Salem, IL. “Our four pharmacies suffer if software is not upgraded successfully. And if there is a problem, the pharmacist always has a key role. We are not big enough to hire an IT guy, so I’m the go-to guy for all our technology housekeeping.”

Vendors can help, Bandy says, and many do help with automated data backup and software updates, telephone support, user groups, and more. But vendors can’t do it all.

“Pharmacists and vendors both have roles,” says Paul Carrig, vice president of technology for PioneerRx, a pharmacy software company. “Dividing up those responsibilities depends in part on what technology you use. We recommend steps for the pharmacist to take to protect their network, but ultimately it is their responsibility to keep their business safe and secure. Consequently, PioneerRx employs many best practices to ensure our users are protected against risks and vulnerabilities.”

In the Workflow
The upkeep of your technology has three fronts:

1. A daily data backup.
2. Regular updates.
3. Security, both physical and virtual.

All three start with the pharmacist.

“Keeping your pharmacy running smoothly starts with recognizing that your technology is as critical to your operations as your staff is,” says Robyn Ambers, a consultant with software vendor PrescrireWellness.

“Engaging in using your technology, training on it, monitoring, and managing it is how you keep it running smoothly,” Ambers says. “You can’t ignore your technology any more than you can ignore your staff and expect them to function optimally on their own. Technology upkeep has to be part of your routine workflow.”

CONTINUED ON PAGE 34>
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Data Backup

Watching data backup is about as interesting as watching paint dry. That’s why most vendors offer automated backup solutions.

“Doing backups is critical,” says Christopher Antypas, PharmD, president and chief operating officer of Asti’s South Hills Pharmacy in Pittsburgh. “The processing and dispensing of medications is the primary piece of what we do. If we were to go down, it would be crippling for us and for our patients.”

Asti’s is three pharmacies in one, a retail operation that does 800 to 1,000 scripts a day, a closed-door long-term-care pharmacy, and a specialty pharmacy that delivers most of its scripts. Antypas backs it all up every night locally and remotely through his vendor.

Other pharmacies use public cloud backup for businesses such as Amazon Web Services or Microsoft Azure Cloud. They send nightly data backups to the cloud, a generic term for servers owned by Amazon, Microsoft, or other vendors which typically store data in multiple locations to increase reliability.

Business-focused cloud vendors offer high data-transmission speeds for quick backup. More importantly, they can provide quick downloads to restore data and get the store up and running in hours. Consumer-focused cloud backup is far cheaper, but downloading to restore data can take days at the transmission rates for consumers.

Backing up only at the pharmacy is as bad as not backing up at all.

“If you make a physical backup on site, you have to physically remove it from the location,” says Tim Tannert, RPh, president of software vendor Framework LTC. “We’ve had pharmacies store their backup in a safe in a store. And when the building caught fire and the safe got hot and the backup media melted, it didn’t help them much.”

Updates

Updating software and hardware is a must. Skipping updates can mean missing out on regulatory changes and falling out of compliance.

The top priority of software vendors is updating their systems and apps to comply with new regulatory requirements, notes Shelly Spiro, executive director of the Pharmacy HIT Collaborative. The group develops health information technology standards that are used throughout the industry.

Skipping updates is also a good way to open your system to attack. Security patches are among the most common software updates. IT security is a cat-and-mouse game with would-be hackers searching for vulnerabilities that open doors into systems. If your system has gotten old enough, vendors stop updating it, which may be a signal that you need to upgrade to a new system.

Pharmacies provide two good targets, warns Shantanu Bhide, vice president of technology for SoftWriters Inc. One is your business and financial information. Hacking into your point of sale system, ordering, adjudication, payroll, or other areas can reap healthy profits for the computer criminal.

Personal health information (PHI) has also become a valuable commodity and pharmacies store vast amounts of PHI, the protection of which is governed by HIPAA regulations. A break in—either virtual or physical—can result in a loss of data, which hurts the pharmacy’s reputation, future business, and bottom line. The fines imposed for

“We’ve had pharmacies store their backup in a safe in the store. And when the building caught fire and the safe got hot and the backup media melted, it didn’t help them much.”

TIM TANNERT, RPH
failing HIPAA data protection requirements can be painful.

Accept your vendor’s updates, Bhide advised. And verify them. “We have seen customers accept a patch, maybe a firewall update to make the system more secure, and it changes access all over the system,” he cautions. “Installing patches is a good thing, but check it out on a test system first to be sure it is not affecting your workflows. Push patches out to your production system only after verification.”

Security
For all the attention focused on hacking and data theft, the reality is that most security breaches are inside jobs; employees or former employees, who steal data or who inadvertently open the way for someone else to hack in. Creating a secure environment starts on the inside, too.

The Ohio State Board of Pharmacy, like many state boards, requires positive identification of the responsible pharmacist on every prescription, notes Randy Myers, PharmD, owner of Harry’s Pharmacy, an independent pharmacy that was founded by his grandfather in Carey, OH.

How to verify identity is up to the pharmacy. “In our system, everybody has a logon and a password,” Myers explains. “I give out the logons, but employees choose their own passwords. Everyone has a specific security level based on their duties. I have friends who have gone biometric with fingerprint scanners. You can scan a badge and type in a password, there are a variety of approaches.”

Staff education is a key element. Tricking or fast-talking someone into revealing confidential information, a practice called phishing, remains among the most successful attacks, Carrig says. Phishing, via web or email, is responsible for most data breaches today, he says. There are numerous email and web filtering tools to help reduce risk from phishing attacks.

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Staying current in the pharmacy profession can be daunting, especially since the amount of information pharmacists are expected to know continuously increases. There were a record breaking 59 new drug approvals in 2018, which is the highest in the past 10 years.

The “Oath of a Pharmacist” that is recited at pharmacy school graduations states: “I will accept the lifelong obligation to improve my professional knowledge and competence.” Staying abreast of professional information in the pharmacy world can include a variety of techniques such as attending continuing pharmacy education (CPE or CE) programs, reviewing drug information updates, and networking. When I taught at Nova Southeastern University College of Pharmacy, I always told my students that it is impossible to memorize everything, but it is important to know how to find the information when you are asked a drug information question.

Continuing Education
Part of the license renewal process requires pharmacists to complete CE for the states where they are licensed. These can include online and live programs. It’s important to check with the state board of pharmacy website what the CE requirements are to ensure that you are ready for renewal. Pharmacists can check with their practice sites and with local state pharmacy associations to see what programs are offered.

“How to Stay Current”

Lea Schilit, PharmD, CPh
Assistant vice president, Eastern Region, Clinical Pharmacy Services for HCA Healthcare
Ambulatory Surgery Division in Ft. Lauderdale, FL.

Schilit uses a variety of different resources to stay current, such as pharmacy journals (eg, American Journal of Health-System Pharmacy), CE programs, and the surgeons and anesthesiologists she works with to inquire about new drugs.

Staying up-to-date with pharmacy laws and regulations is a high priority for her, and she relies on updates through CE programs, her colleagues, communication from the Florida Board of Pharmacy, and through her company.

Schilit provides quarterly education to the surgery center staff. “The topics include diversion, safe injection practices, high alert medications, and new drug reviews, among others. I also speak at ambulatory surgery and anesthesia conferences on topics such as medication safety and diversion,” says Schilit.

In addition, Schilit has also spoken at her annual medical director’s conference on medication safety and on monthly safety and quality calls.

Clinical Pharmacology, PubMed, and Up-to-Date are Schilit’s go to resources when she searches for drug information.
“The FDA website offers the most current information on drug approvals, recalls, and important safety alerts. For updates on vaccines and public health information, the CDC is your go-to resource.”

Certificate Programs
Pharmacists who are interested in expanding their professional horizons should look at the certificate programs available through the ASHP and APhA. Medication therapy management (MTM) is a popular program offered through APhA that teaches pharmacists how to develop and deliver MTM services in their practice setting. Other APhA certificate programs include cardiovascular disease management, immunizations, and diabetes care. ASHP offers a variety of certificate programs include pharmacogenomics, pain management, medication safety, and teaching.

There is a Sterile Product Preparation Certificate Program that was launched by ASHP to train pharmacists in all aspects of sterile compounding.

Certificate programs provide CE credits and are a great way for pharmacists to enhance their knowledge base. Be sure to add these certificate programs to your CV when you are applying for jobs.

Drug Information Updates
PubMed is a free resource for accessing clinical studies from journals. Some articles are available as full text, and if your pharmacy practice site subscribes to an electronic library, then most articles can generally be accessed for free. Guidelines are also available through PubMed. It is especially important to stay current on the new recommendations for pharmacy practice for disease states including diabetes, HIV, hypertension, and hyperlipidemia.

Establishing a monthly journal club where pharmacists and students sit and discuss recent clinical studies can help everyone stay up-to-date.

Some journals, like the New England Journal of Medicine, allow individuals to register for free email alerts of published clinical studies and allow access to three full-text articles per month.
“Social media is a great tool for pharmacists to stay current. Twitter, Facebook, and LinkedIn are all free, and it is easy to set up professional profiles.”

This is a great way to review clinical studies relevant to your practice setting from a highly reputable peer-reviewed journal.

Be a Preceptor
Serving as a preceptor—teaching the next generation of pharmacists—is also a great way to stay current. When I was pharmacy preceptor, I found that I learned so much valuable information from my students, especially from their questions. Giving drug information questions to students on topics that you are interested in learning more about can help you and your colleagues stay up-to-date. Students also benefit from this exercise by using reputable resources to formulate the best response to these drug information questions. If you are a preceptor, check with the pharmacy school because you may also have free access to electronic drug information resources.

Free Websites
There are a variety of free websites that offer great drug information and legal and regulatory updates for pharmacists. You can sign up for email alerts from many of them. The FDA website offers the most current information on drug approvals, recalls, and important safety alerts. For updates on vaccines and public health information, the CDC is your go-to resource. The CDC also has a free app for your smartphone with charts for adult and childhood immunizations.

DailyMed, a website of the National Library of Medicine, is a nice one-stop-shop for medication prescribing information created by the National Library of Medicine. It also allows you to report adverse drug reactions, search for clinical studies, and identify pills.

The DEA website contains the Controlled Substances Act which includes federal laws that pharmacists should know as part of the profession. The website, which include important elements of controlled substance prescriptions.

Social Media
Social media is a great tool for pharmacists to stay current while managing their busy careers. Twitter, Facebook, and LinkedIn are all free, and it is easy to set up professional profiles. These tools can also be accessed through apps on your smartphone for staying up-to-date from anywhere. Pharmacists can follow professional organizations and drug information resources for the latest information on health news, drug approvals, clinical studies, and pharmacy law updates. Pharmacists can learn from the members’ posts which include medication questions, vaccine information, and career opportunities.

Pharmacists can also educate the public through social media, such as the importance of vaccinations to prevent measles outbreaks. One of my favorite Facebook groups is the Pharmacist Moms Group, which provides support for women pharmacists.

Networking at Conferences
Networking at pharmacy conferences is a great way to expand professional pharmacy opportunities. Consider presenting a pharmacy poster at an ASHP or APhA national conference. You will often have great discussions about your poster with colleagues and learn about groundbreaking research. Be sure to bring business cards with you along with your poster abstract to distribute at the conferences.

Useful Websites for Staying Current
- NABP’S CPE MONITOR: https://nabp.pharmacy/cpe-monitor-service/plans/
- NABP’S LIST OF STATE BOARDS OF PHARMACY: https://nabp.pharmacy/boards-of-pharmacy/
- ASHP’S CONTINUING EDUCATION: https://www.ashp.org/Professional-Development/Continuing-Education
- APHA CERTIFICATE TRAINING PROGRAMS: https://www.pharmacist.com/apha-advanced-training-programs
- ASHP CERTIFICATE PROGRAMS: https://www.ashp.org/Professional-Development/Professional-Certificate-Programs
- FDA: https://www.fda.gov/
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- DEA: https://www.dea.gov/
- DRUG TOPICS: https://www.drugtopics.com/
In March, the FDA approved brexanolone (Zulresso, Sage Therapeutics, Inc.) for treatment of postpartum depression in adult women. Brexanolone exerts its effect by modulation of GABA_A receptors. It is the first medication approved specifically to treat postpartum depression.

**EFFICACY**

The efficacy of brexanolone was studied in two randomized double-blind placebo-controlled multicenter trials (study 1 and study 2) in 247 adult women (age 18 to 45 years). Eligible participants had been diagnosed with moderate (study 2) to severe (study 1) postpartum depression and met DSM-IV criteria for a major depressive episode with onset within the third trimester (24%) or within four weeks after delivery (76%). Oral antidepressant use was not an exclusion criterion; 23% of women reported taking oral antidepressants at baseline.

Participants in the study received a continuous infusion of brexanolone or placebo for 60 hours. In both studies, brexanolone was titrated to a target dose of 90 mcg/kg/hour. Study 1 also evaluated a target dosage of 60 mcg/kg/hour. The mean change from baseline depressive symptoms as measured by HAM-D total score at hour 60 of the infusion serves as the primary endpoint. An additional measurement and comparison to baseline scores at day 30 serves as the secondary endpoint.1

Participants returned to baseline within 15 to 60 minutes of dose reduction or interruption. If hypoxia occurs, stop the infusion and do not restart. Patients must also be accompanied during interactions with their children. Other adverse effects seen in trials include dry mouth and hot flashes.

Brexanolone should be avoided in patients with end stage renal disease due to the inability to clear the solubilizing agent used in the product. Coadministration of medications with CNS depressant effects may increase the risk of sedation-related adverse effects.

**SAFETY**

In studies, brexanolone was associated with a loss of or altered consciousness. This adverse effect was not associated with the placebo. Adverse effects related to consciousness were not associated with pattern or timing of dose or preceded by sedation or somnolence in all patients. The manufacturer includes a warning about excessive sedation and sudden loss of consciousness. It has restricted availability through the Zulresso Risk Evaluation and Mitigation Strategy program.

Participants must have continuous pulse oximetry monitoring and be observed for excessive sedation and loss of consciousness every two hours during nonsleep times when the infusion is administered. In the event of excessive sedation, stop the infusion immediately. The infusion may be restarted at the same or lower dose after symptoms resolve. Participants returned to baseline within 15 to 60 minutes of dose reduction or interruption. If hypoxia occurs, stop the infusion and do not restart. Patients must also be accompanied during interactions with their children. Other adverse effects seen in trials include dry mouth and hot flashes.

Brexanolone should be avoided in patients with end stage renal disease due to the inability to clear the solubilizing agent used in the product. Coadministration of medications with CNS depressant effects may increase the risk of sedation-related adverse effects.

Kathryn Wheeler PharmD, BCPS, is associate clinical professor of pharmacy practice at the University of Connecticut, School of Pharmacy, Storrs, CT

**REFERENCES**

Training the Technicians

I've written a couple of articles about staffing levels, which is the number one concern of community pharmacists. I always say the difference between a good day and a challenging day isn't the prescription volume, but rather the number and quality of technicians. Lots of formulas exist for the quantity of technicians, but no one can figure out the quality part of the equation.

I hired my first full-time technician in 1984. Darlene O'Connell was 13 years older than me (I was 26), and she was amazing. She could do everything with great neatness and accuracy. When it came to filling out the triplicate NCPDP carbon copy claim forms she was a dynamo. About 10% of all our prescriptions were billed to insurance back in those days.

Once the computer system became an intrinsic part of pharmacy operations in 1987, Darlene's role changed. I did the data entry and Darlene counted pills and managed the inventory. She was hardworking and never brought drama to work with her.

When I left that small independent chain in 2008, knowing it was going to be sold to one of the big three chains, working with Darlene is what I missed the most. I spent more of my waking hours with her in those days than I did with my own wife.

When I started working for Thompson Pharmacy, my role changed. Techs did all the data entry and the pharmacist did the verification and managed inventory. We had a high school kid named Brad Wigand who talked to me as graduation approached. He said he had no interest in attending college and wanted to go to a technician school to become a pharmacy tech. I told him that was a great idea, and asked what type of pharmacy practice he was interested in. He said he'd love to work for Thompson's as a tech. I told him to save the $12,000 tuition and I could train him to do everything that we need him to do as a community pharmacy technician.

Brad has a great aptitude for computers and caught on quickly, learning the nuances of billing, split billing, and monitoring underpayments. He calculates insulin day supplies as accurately as I do. He simply is the best data entry tech I've worked with. We had him on a long leash and let him polish his skills. Most of all we saved him a year of employment and $12,000!

I know pharmacy technicians who went to a formal tech school and took out loans and owe more money now than they borrowed. Brad doesn't need to know IV preparation, how to fill Pyxis machines, or any of the other skills that a hospital pharmacy technician needs to know.

Technician hours are set by corporate for most pharmacy operations. We can argue and fight with supervisors about levels of staffing. The in-house training of technicians falls directly on the pharmacy staff with ultimate responsibility landing on the shoulders of the pharmacist.

If our technicians are poorly trained, it is our fault. If they don't know how to calculate day supplies or abbreviations, we need to take time to coach them along. Most of all we need to give them the opportunity to learn the software and not just push them away from the keyboard and do it ourselves.

Jim Gregory is our local representative in the Pennsylvania legislature. He texted me about legislation requiring registration of pharmacy techs and to ask about my position on the subject. I texted him back, "Registration—yes, Licensure—no."

I have no problem with our employees being registered to work in the pharmacy, but they do not need to be licensed since they are technicians. The word technician is derived from the ancient Greek "tekton," meaning "to work with one's hands."

Whether it is Darlene or Brad, our job is to give our technicians the knowledge to work with their hands, to benefit us as pharmacists and our patients.

Peter Kreckel works in an independent pharmacy in Pennsylvania. You can reach him at editors@drugtopics.com.

Peter A. Kreckel, BSPharm

“Training the Technicians”

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INCREASE PATIENT SAFETY

“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

Liberty Software
Revolutionary Pharmacy Software

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