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Remember the first and one of the most important lines in the Oath of a Pharmacists? You likely recited it at least a few times in your career—during your white coat ceremony, your graduation, and attendance of either of these ceremonies. It is: “I promise to devote myself to a lifetime of service to others through the profession of pharmacy.” It is followed by another important statement: “I will hold myself and my colleagues to the highest principles of our profession’s moral, ethical, and legal conduct.”

Two Arizona pharmacists made headlines when it seems they may have not adhered to this pledge.

In the first case, a community pharmacist chose not to fill a hormone prescription for a transgender patient. Based upon news reports, the pharmacist apparently denied filling the prescription and continually asked the patient why she needed the therapy, in front of other customers. The patient claimed the pharmacist refused to give her back the written prescription, forcing the prescriber to call in a new prescription to another pharmacy. The patient reported feeling “mortified.” She eventually filed a complaint with the Arizona State Board of Pharmacy.

In the second case, a nine-week pregnant woman was told by her prescriber that there was no fetal heartbeat and that her pregnancy would likely end in a miscarriage. The woman had two options: have a surgical procedure to remove the fetal tissue or take a medication, i.e., misoprostol, to produce a miscarriage. She chose the latter.

When she presented the prescription to the community pharmacy, the pharmacist refused to fill it based upon “ethical beliefs,” and refused to give the prescription back. The patient left the pharmacy feeling “ashamed” and “humiliated,” and contacted her husband. The husband came to the pharmacy to explain the situation, but the pharmacist continued to refuse to fill the prescription. Eventually, the pharmacist sent the prescription to another pharmacy location where the patient was able to pick up the medication. She also filed a complaint with the Arizona State Board of Pharmacy.

In both cases, the pharmacists refused to fill the prescriptions based upon personal moral objections. And while I may morally disagree with their actions, they legally had the right to refuse to fill the medications.

Arizona is a state with a law that allows pharmacists to refuse to fill a medication because of “sincerely held religious beliefs.” However, pharmacists must make a good faith effort to refer or transfer the prescription to another pharmacist to meet the clinical needs of the patient in a timely manner, as required by the Arizona law. By not doing so, pharmacists may end up getting fired (as was the case with the pharmacist who refused to fill the hormone prescription), and they may be investigated by the State Board of Pharmacy.

If you live in a state that allows you to refuse to fill a medication based on moral or religious beliefs—and you have beliefs that could lead you to refuse—consider identifying pharmacists to whom you will be able to refer prescriptions. If you are a pharmacist who does not hold such beliefs, offer to be a referral for pharmacists who do. Also, review your own company and state policies to clarify how you should effectively manage a prescription that you are morally conflicted about.

Doing so will allow you to continue to devote your lifetime of service to not only patients, but other pharmacists as well.
Express Scripts’ 2019 Formulary Exclusions

Express Scripts’ 2019 National Preferred Formulary excludes certain blockbuster drugs. It also removes new categories of medications that the PBM had shied away from excluding in the past.

The annual list of excluded medications encompasses 48 new medications, including the anticoagulant dabigatran (Pradaxa), the hepatitis C medication sofosbuvir (Sovaldi), and the HIV antiviral combo drug efavirenz/entecavir/tenofovir disoproxil fumarate (Atripla).

New therapy areas with excluded drugs include hemophilia, HIV, and hereditary angioedema.

“The reasons for the exclusions are likely multifactorial. One reason could be changes in cost, but it may also be due to the increased competition within the class,” Jeremy Schafer, PharmD, senior vice president at Precision for Value, tells Drug Topics.

Schafer is concerned about the exclusion of drugs for rare diseases, such as hemophilic factor (Xyntha) for hemophilia A, and C1 esterase inhibitor (Berinert) for hereditary angioedema. “Patients may be started on these products in the hospital and then discharged home. Will the patient be stopped by an exclusion and have a delay in therapy as the doctor files for a prior authorization or considers an alternative?”

However, Express Scripts says formulary preference is given to high-value therapies with the lowest net cost for clients, achieved through low list price, rebate or both. For example, efavirenz/ lamivudine/ tenofovir disoproxil fumarate (Symfi, and Symfi Lo) are preferred to treat HIV-1. Those medications have 40% lower list prices than Atripla.

Meanwhile, CVS Health will likely announce its 2019 formulary changes in early October. It is expected to exclude 23 drugs, and add four.

Online Pharmacy Delivery Service Threatens Amazon, Drug Stores

Amazon and PillPack have yet another major competitor in the growing online pharmacy business—and drug store chains have reason to be concerned.

New York-based Capsule, which boasts same-day delivery for prescriptions and a frictionless, personal pharmacy experience, recently landed $50 million in funding. The funding boost will allow Capsule, currently operating in New York City, to expand nationwide in the future.

After Amazon acquired PillPack, which delivers medications in presorted dose packaging and coordinates refills and renewals, earlier this summer, drug store chains’ stock sank. CVS Health, Walgreens...
CVS MinuteClinic Adds Video Visits

CVS Health’s MinuteClinic recently launched Video Visits, which will provide patients with access to healthcare services 24 hours a day from their mobile devices. MinuteClinic partnered with Teladoc to offer Video Visits, which are initiated through the CVS Pharmacy app.

“Patients who opt to seek care through a fully customized MinuteClinic Video Visit experience the same high-quality, evidence-based care they receive at traditional MinuteClinic locations inside select CVS Pharmacy and Target stores,” CVS Health says. The Telehealth service is for patients with minor illnesses and injuries. MinuteClinic charges $59 for the visits, and will add insurance coverage over the next few months.

The service is available in nine states—Arizona, California, Florida, Idaho, Maine, Maryland, Mississippi, New Hampshire, and Virginia—and Washington, DC. CVS Health expects Video Visits to be available nationwide, where allowed, by the end of this year.

Contaminated Synthetic Marijuana Products Killing Users

The FDA is warning about severe illnesses and deaths from the use of contaminated synthetic cannabinoi (marijuana) products.

The products, sold at convenience stores and gas stations, are contaminated with brodifacoum, a very long-acting anticoagulant commonly used in rat poison. The marijuana substitutes are sold under the names “K2,” “Spice,” and others.

Over the past few months, hundreds of individuals in about 10 states have been hospitalized after experiencing severe bleeding. Several deaths have also been reported, according to a statement from the FDA Commissioner Scott Gottlieb, MD, and other officials.

“Use of these illegal products pose significant public health concerns for both individuals who may use the contaminated products and the U.S. blood supply, as there is the potential for contamination of blood products donated by those individuals who have used these substances,” say the FDA officials.

A number of synthetic marijuana products are being illegally marketed. The FDA has worked with the DEA to place several synthetic cannabinoids into Schedule I of the Controlled Substances Act to avoid an imminent hazard to public safety.

“Individuals who have possibly used synthetic marijuana products should be vigilant for signs of bleeding. These include easy bruising, oozing gums, and nose bleeds. People experiencing these symptoms after using synthetic marijuana products should immediately seek medical attention, as the effects of brodifacoum are treatable,” Gottlieb and his colleagues say.

“We also want to alert healthcare providers, particularly those delivering care in emergency settings, to be aware of these risks and consider the possibility of synthetic cannabinoid exposure when individuals present with unexplained bleeding. Standard coagulation tests, such as the prothrombin time, can be dramatically elevated in these settings, and prompt treatment with high doses of vitamin K and other supportive care can potentially be life-saving,” Gottlieb and his colleagues add.

Boots Alliance, and Rite Aid collectively lost more than $11 billion in stock market value the day the news was announced.

Capsule Founder and CEO Eric Kinariwala doesn’t seem fazed by competitors such as PillPack. “We’re definitely excited to see that Amazon has entered the space with PillPack, as its further validation that the conventional pharmacy experience is broken. Increased momentum toward fixing the problem is great for everybody,” he tells Drug Topics.

Capsule differs from other online pharmacies and traditional brick-and-mortar drug stores, Kinariwala contends. “Traditionally, digital commerce companies have used their technology to remove human interaction, but at Capsule, we’ve built our platform to amplify its power in your healthcare.”

For example, Capsule handles patients’ prescription refills, and coordinates with doctors and insurance companies, so consumers don’t have to deal with them when filling scripts. It promises to provide caring, friendly service in which consumers “never have to wait in line again.” The company website says, “Never talk to a voicemail autobot. Text, call, email, or chat with your pharmacist whenever is convenient.”

In addition, Capsule is not simply “layering on” delivery services, like many conventional pharmacies, Kinariwala says. “Our view is that delivery will become a commodity and that it is only part of the solution. Where Capsule differentiates is that it’s been specifically designed to connect humans and technology at every point to create value for all the stakeholders in healthcare.”
How Patients Really Feel About Opioid vs. Nonopioid Meds for Chronic Pain

A new study investigated pre-existing perceptions about pain medications by individuals with chronic pain and how these perceptions relate to patients’ experiences with these medications.

The study, published online in the Journal of Pain, the journal of the American Pain Society, found that, despite strongly held beliefs about opioid and nonopioid medications, patients were often surprised by their results.

The study provides insights into the results of “The Strategies for Prescribing Analgesics Comparative Effectiveness” (SPACE) trial, which compared benefits and harms of opioid versus nonopioid medications over 12 months for chronic musculoskeletal pain. SPACE found that opioid meds were not better at improving pain that interfered with walking, work, or sleep over 12 months for individuals with chronic back pain or arthritic hips or knees compared to nonopioid medications. SPACE also found that adverse medication-related symptoms were more common in the patients who took opioids.

For the Journal of Pain study, Marianne Matthias, PhD, Regenstrief Institute investigator, and colleagues, interviewed 34 SPACE participants, all of whom were patients at a VA hospital.

“Patients’ expectations do not always match their experiences,” says Matthias. “Patients in this study, who for the most part believed that opioids were the strongest pain medicines available—even if they didn’t want to take them—were often surprised when either: 1) the opioids didn’t work as well as they thought (for patients randomized to the opioid arm), or 2) when nonopioids, such as NSAIDS or topical creams, helped reduce their pain much more than expected (for patients randomized to the nonopioid study arm). Most patients seemed not to be aware of the large number of options available to them or that many of these (nonopioid) options can actually be quite effective for pain relief.”

“Some patients described having lower pain on opioids but not being able to do much of anything because of the lethargy associated with these medications.”

—Marianne Matthias, PhD

In addition, patients in many cases learned that function was more important than pain levels, according to Matthias. “In other words, some patients described having lower pain on opioids but not being able to do much of anything because of the lethargy associated with these medications. On the other hand, some patients who took nonopioids described being able to do more—be active, play with their kids, etc. It would be important . . . to work to manage patients’ expectations to keep patients open to trying a number of other treatment options, and to shift patients’ focus from pain levels/intensity to function, i.e., what they are able to do.”

Christine Blank is a contributing editor.

Opioid Dosages Increase, Despite Awareness

The dosages of opioids increased over a 10-year period in the United States, particularly among disabled Medicare beneficiaries.

In the study, published in the August issue of BMJ, lead author Molly Moore Jeffery, PhD, scientific director of emergency care research at Mayo Clinic, wrote that disabled Medicare beneficiaries had the highest rates of opioid use, the highest rate of long-term use, and the largest average daily dose.

The retrospective cohort study of administrative claims data examined opioid prescribing trends from 2007 to 2016. Researchers examined data from 48 million individuals, including commercial beneficiaries, Medicare Advantage beneficiaries aged 65 years and older, and Medicare Advantage beneficiaries less than 65 years old (due to permanent disability).

In the group of patients on permanent disability, both quarterly use rates (39%) and average daily dose (56 mg morphine equivalents or MME) were higher at the end of 2016 than the low points observed in 2007 for each end point (26% prevalence and 53 MME).

“Opioid use and average daily dose have not substantially declined from their peaks, despite increased attention to opioid abuse and awareness of their risks,” Jeffery writes.
A certification program in compounded sterile preparation (CSP) will benefit both pharmacy technicians and pharmacists, and indicates how the technician’s role is evolving.

Since the program launched last December, the Pharmacy Technician Certification Board (PTCB), has granted more than 300 Compounded Sterile Preparation Technician (CSPT) certifications. These certify pharmacy technicians in the compounding of medications prepared using aseptic techniques.

“Certifying technicians who prepare CSPs with the CSPT Certification helps advance the level of medication safety and strengthens the pharmacy team,” William Schimmel, executive director and CEO of PTCB, tells Drug Topics.

In addition to improving medication safety and offering professional advancement opportunities to technicians, the certification can assure pharmacists in charge of final checks on CSPs that their CSPTs are knowledgeable and qualified to compound IV solutions, including chemotherapy IVs.

CSPs are made in hospitals and health systems, at infusion centers, community pharmacies, and compounding centers. In hospitals for example, with the assistance of a CSPT, pharmacists would have more time to devote to safety checks, and preparing drugs for IV use and other regimens.

An Advanced Certification
An advanced certification represents an opportunity for technicians to move up in their careers. In addition, the certification improves patient safety for the overall benefit of the pharmacy.

“The new certification reflects the changes that are happening in the pharmacy profession as pharmacists play a greater role in the delivery of healthcare,” Schimmel says. “The CSPT certification is another rung on a career ladder for technicians. Motivated, professional teams with low turnover are going to perform better. This can contribute to better medication outcomes and decrease long-term costs,” he says.

Certification would really help the smaller pharmacies, which have limited staff for training.”

CHERI GARVIN, RPh.

Long Time Coming
The CSPT program is the first new certification program PTCB has offered since the organization was founded in 1995.

Allen L. Horne, RPh, an oncology pharmacy specialist at Palmetto Health Richland, Columbia, SC, says, “Technicians are finally being rewarded for their knowledge of sterile compounding. Now they can bring a new level of expertise to the IV team, and raise the level of safety and quality.”

Horne, who chaired the CSPT Exam Development Committee, explained that his hospital is developing a career ladder for pharmacy technicians since the certification was created. “With CSPT certification, the technician may rise up a level on the ladder and be recognized as being set apart from beginning technicians. Depending on their current level on the career ladder, they may also be incentivized through salary increases.”

“CSPT certification raises the safety and quality level of sterile product preparation, and frees up hospital pharmacists, giving them added time to calculate dosing, review drug regimens, and generally devote more time to supervisory tasks, including checking patient records for drug interactions,” Horne adds.

Cheri Garvin, RPh, CEO of The Compounding Center, a compounding pharmacy in Leesburg, VA, says that her pharmacy already uses technicians in sterile compounding. “Still, I would definitely consider the (CSPT) certification for our technicians,” Garvin says. “Certification represents a more standard approval and would be better than one person training another,” she adds, noting that certification would expand a technician’s knowledge base and help improve career opportunities. “Certification would really help the smaller pharmacies, which have limited staff for training,” she noted.

A CSPT must recertify each year, which requires completing five continuing education hours in sterile compounding and the submission of a supervisor’s attestation form, according to PTCB.

Joseph Constance is a writer in Wyckoff, NJ.
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The move toward value-based reimbursement can be a plus for health-system pharmacists. Pharmacists can help health systems develop and meet benchmarks and performance targets in accountable care organizations (ACOs), bundled payment models, and other value-based systems.

To help the C-suite recognize their value, pharmacists must show them that pharmacy is a cost-saver, says Michael Korczynski, PharmD, BCAP, manager of clinical services, Pharmacy-Ambulatory Care, for Allegheny Health Network in Pittsburgh. “Dispensing medicine is about 1% of my career. I’m a provider of medication management services, educating patients, educating staff, ordering labs, ordering referrals, being a contributor to the development of policy and procedure.”

Grow awareness
Korczynski is hardly an outlier. Pharmacists nationwide are following examples set by Kaiser Permanente, Geisinger Health System, the VA, and other integrated health systems that rely on pharmacists for comprehensive medication management services. “These systems are so integrated that physicians and pharmacists work in a shared success model where the number one goal is to focus on the disease state,” says Fred Pane, RPh, senior director for pharmacy at Coordinated Health. “While you are taking cost out what is important to them, and weaving a story that resonates around quality, revenue, and spending.”

Act now
The key step in helping an organization meet value-based targets is getting leadership to buy in. But don’t wait until value-based contracts have been signed. “You have to have a seat at the table when quality, financial, and clinical are discussing and following up on value-based plans,” says Ashley G. Woodhouse, PharmD, manager of the St. Joseph’s/Candler Centers for Medication Management in Savannah, GA. “You have to know exactly what kind of value-based plans are being considered, the benchmarks being used, and what is not being assessed even if we know it should be.”

ACOs that track costs using the Medicare Savings Program, for example, are focused on Part B costs. Leaders need and want pharmacy to help manage Part B medications. “What you, in pharmacy, focus on,” Woodhouse says, “depends on the value-based programs your system is involved with.”

Fred Gebhart, a contributing editor, says, “The level and complexity of drug therapy today is such that you cannot manage either outcomes or costs without the assistance of a pharmacist.”

Make the case for pharmacist involvement:
Think like the C-suite. Learn what is important to them, and weave a story that resonates around quality, revenue, and spending.
In the midst of President Trump’s plan to lower drug prices for consumers and shaming Pfizer over price jumps, several pharma makers such as Novartis and Merck are saying that they will try and limit drug price increases. Are these drops just a response to political pressure or will the momentum last? Here’s what industry watchers say:

**Daniel B. Vukmer, Esq,** CEO, Tampa Bay Health Alliance, LLC, and chief strategy officer, USF Health

“I think what we’re seeing is an aberration based on short-term political pressures and nothing more. Regardless of price freezes or reductions, per capita spending on prescription drugs has continued to rise for more than 20 years and I don’t anticipate a long-term reduction.”

**Michael Thompson,** president & CEO, National Alliance of Healthcare Purchaser Coalitions:

“We welcome this respite in drug price increases, but are concerned about the longer-term implications of these limitless pricing strategies. There needs to be action to foster greater competition where possible and insist on greater pricing equity across the globe. Limitless pricing, even on high-value drugs, is breaking the affordability of the entire U.S. healthcare system.”

**Kimberly Lenz,** PharmD, clinical pharmacy manager in the University of Massachusetts Medical School’s Office of Clinical Affairs:

“Several other drug manufacturers have come forward with similar pledges—mostly window dressing. While they may sound good at face value, there are a lot of caveats to these pledges or the timing of their pledge that limit their impact.

Merck pledged to reduce prices by less than or equal to 10% for their medications, but it does not include some of their blockbuster drugs including Keytruda or Januvia; and they announced a 60% price drop on Zepatier, which has already been replaced by other newer HCV therapies. Roche hiked cancer drug prices before pledging to keep them flat.

In general, we need more than these ‘pledges.’ We need a more systematic change.”

**Chris Skisak,** executive director, Houston Business Coalition on Health:

“This seems to be a momentary pause in price gouging made out of political necessity rather than a true re-evaluation of how prices are set. Even if the drug companies freeze their prices it does nothing to address the current lack of transparency to the purchaser (consumer and employer) in the market. It is no accident that pharmaceutical middlemen are now near the top of the S&P 500.”

**Bonnie Greenwood,** PharmD, BCPS, clinical program director in the University of Massachusetts Medical School’s Clinical Pharmacy Services:

“Although I want to believe these pledges will have a real impact, I am skeptical that they amount to a public relations response to ongoing consumer ire and public shaming by government officials. I appreciate that Scott Gottlieb has been quite vocal about addressing drug prices and hope continued efforts by the FDA will begin to make some headway.”

**Joseph Honcz,** RPh, MBA, vice president, Payer Access Solutions for Precision for Value

“It happened in the 1990s and it’s happening again today. No, not the reemergence of high-waisted flare jeans, but pharma’s pricing response in light of strong political rhetoric. As noted in a 2006 RAND study, during the early 1990s, pharma moderated
price increases as a way to avert regulations to great success. The recent pullback by Pfizer and the softened stance of Novartis appear to be similar guideposts from the 1990s for the rest of the industry to heed in order to avoid regulation.

And like the flare jeans of the 90s, if successful, the recent pharma pricing actions may soon fade away.

That being said, this isn’t your typical administration and one should consider the potential for increased durability of the various tactics they are considering from public shaming to reimportation and beyond.

David Pittard, managing principal, OneDigital:

Prescription drugs must be one of the only ‘goods’ in the market where new entrants provide credence for existing suppliers to raise the price. When Norvartis rolled out Costonyx a few years ago, Amgen and AbbVie immediately increased the prices of Enbrel and Humira, respectively. The result of the new prescription has been over a 200% price increase for the existing medications in a five-year period.

Historically, drug manufacturers have justified their high prices for having to compensate for years of R&D, public sector health plan reimbursements, and limited patent rights. That could be more justified in the initial years of the drug being released into the market; but, significant increases many years later is unjustified.

Tracey Walker is content manager for Drug Topics’ sister publication, Managed Healthcare Executive.

TRUMP’S PLAN TO LOWER DRUG PRICES

Karen Appold

In June, President Trump unveiled his plan to lower drug prices, “American Patients First.” Trump blames high drug prices on foreign governments, middlemen such as pharmacy benefit managers, the expiration of some key patents, an opaque business model around drug pricing, and complicated laws and regulations. In his plan, Trump cites three key elements.

1. Improved Competition.

Trump says the FDA needs to take steps to prevent the gaming of regulatory processes, where drug companies game current regulations to block competition from generics, which keeps prices higher. He also says he wants the FDA to educate consumers on biosimilar biologics, which could lead to more uptake of less expensive medications.

Some experts say an important element of improving competition is addressing patent protection problems. “Improved competition can only be achieved by reducing the period of patent protection, allowing for brand drugs to convert to low-cost generics,” says Thomas Borzilleri, CEO and founder, InteliSys Health, a drug price transparency provider.

2. Better Negotiation.

One of Trump’s strategies to achieve this includes experimenting with value-based purchasing in federal programs. Trump wants to allow Medicare Part D to switch out generics in a formulary during a plan year if a price spikes and allow Part D plans to negotiate drug prices with manufacturers like private health plans. Trump would also like to explore putting tariffs or other restrictions on foreign countries buying domestic drugs.

J. Bart McCollum, JD, president and chief operating officer, Ameriflex, a healthcare benefits administration firm, believes this is a misguided approach. “Increasing the prices foreign countries pay will not necessarily lower prices that Americans pay,” he says.

Says Leah Binder, president and CEO, The Leapfrog Group, a healthcare nonprofit, “Medicare negotiation would not necessarily lower prices for the 185 million working Americans covered by employers. Indeed, a good deal for Medicare could make it more difficult to control pricing for everyone else.”

3. Incentives for Lower List Prices.

Trump may require drug manufacturers to include list prices in advertising to increase transparency. He’d also like to require Medicare’s drug-pricing dashboard to make price increases and generic competition more transparent. Trump might also limit rebates on prescription drugs, which the Administration has suggested may obscure drug prices.

“The right reforms in this area could help Americans access lower list prices and out-of-pocket costs,” says Meena Datta, JD, partner and global co-leader, Sidley Austin LLP Healthcare Team, an international law firm. “The wrong reforms could make matters worse or cause new problems.”

Karen Appold is a medical writer in Lehigh Valley, PA.
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Drug costs are increasing, and so is patient cost sharing. That’s raising serious problems for some patients. Here are seven of the most out-of-reach drug categories, according to industry watchers.

1. Biologic Drugs

High prices for drugs generally exist when they are patented and serve a specific need with little or no good lower-cost alternatives, according to Ed Francis, senior director and leader of life sciences for West Monroe Partners. The high-cost prescriptions today tend to be for biologics. “The costs will come down as patents expire and biosimilars come into the market,” he says. Biosimilars are more complicated to make than small molecule generics, so there will be some delays in bringing them online. “Ultimately the price may still be higher than a typical small molecule drug,” he says.

2. Rare Disease Drugs

Eculizumab (Soliris), which is for treatment of myasthenia gravis, has an annual cost of over $500,000, according to John Sarich, VP of strategy, VUE Software, which specializes in innovating and automating business processes. “The 39 most expensive drugs in the U.S. range from an annual cost of low $10,000s to high $500,000s,” he says. “They are designed to treat very serious medical conditions. It should be noted that pharmaceutical companies are international businesses with drug manufacturers spread throughout the world. While subsidies abound, the United States does, in fact, pick up a disproportionate share of the drug costs.”

3. Cancer Drugs

More than half of new cancer drugs approved by the FDA from 2009 to 2013 were priced at more than $100,000 for one treatment for a year, says Yvonne Tso, a consultant in the healthcare practice of AArete, a global management consultancy. “In 2015, cancer patients were paying from $7,484 to $21,834 a month to take new breakthrough drugs that could help them survive.”

4. Some Combination Drugs

“Employers and plan members need to be aware of high-cost ‘combo’ drugs where two or more inexpensive drugs are mixed together and marketed as a new’ expensive drug,” says Cheryl Larson, president and CEO of the Midwest Business Group on Health. One example is Duexis. “The cost is about $1,080 for a 30-day supply, but what many don’t know is that this is a combination of two inexpensive drugs—ibuprofen and famotidine,” Larson says, noting that a 30-day supply of ibuprofen is less than $10 and famotidine is less than $5.

5. Abuse-Deterrent Formulation (ADF) Opioids

“Extended release ADF opioids are often much more expensive than generic opioids, says Chin. “Although it would be a societal benefit if less opioids were abused, the question is who should bear the increased cost?”

6. Opioid Overdose Reversal Drug

Naloxone has been available in generic intravenous formulation for decades, according to Chin. “In the past five-plus years as the opioid crisis has intensified, use of this medication has skyrocketed along with the price. There are several formulations available on the market at present.” In 2014, the FDA approved Evzio naloxone auto-injector. The price was around $690 retail then, “but in 2017 the price increased to $4,500,” says Chin. “Several of my patients have been unable to afford the copay for this medication so I have changed to prescribing Nasal Narcan, a brand-name product with a retail price around $135.”

7. Some Chronic Condition Maintenance Drugs

Drugs for chronic condition maintenance can be out of reach for those on a fixed income, Tso says. A 30-day supply of metformin extended-release tablets (1000 mg, 60 tablets) is more than $3,900, and metformin is a generic. One-month of Lantus (insulin), is more than $1,000. Advair and Symbicort inhalers are $250 to $350 a month, she says. 

Tracey Walker is content manager for Drug Topics’ sister publication Managed Healthcare Executive.
Why Pharmacists Have It Tougher Than Anyone Else

Ever feel like you just can’t win as a pharmacist? You’re not the only one.

1. Everything—and I do mean everything—is our fault, even when we are nowhere near the scene of the crime.

People blame it on the pharmacist more than they do the alcohol. This month’s copay higher than last month’s? The pharmacist did it. Computer freezing this morning? A diabolical pharmacist hacked it. Global warming? Pharmacists’ conspiracy. Can’t find your homework? Your starving pharmacist ate it.

2. An eavesdropping patient can—and almost always will—undermine our best patient consultation.

Ever spend time counseling a patient on a new prescription only to have a nosy passerby swoop in and interrupt to give unsolicited advice? So much for all that fancy pharmacy school training! You must now invest extra time undoing the damage—especially if the information is wrong. Part of the damage control involves convincing your patient that you actually know what you’re talking about.

3. Everyone thinks our only skill is putting pills in sacks.

Every pharmacist I know once had dreams and aspirations, and I assure you that putting pills in sacks never has made the list, yet somehow, it has become our trademark. We all know that our day-to-day job duties entail much more than verifying a prescription, regardless of where we work. But how many times do you get told when you perform a task beyond the stereotype, “I didn’t know pharmacists could do that.”

4. Patients think we’re idiots because we haven’t heard of that new diet pill on TV.

Newsflash: We don’t watch commercials anymore—we have Netflix. And that latest wonder pill likely has not been evaluated by the FDA for safety, so it’s not really on our radar.

5. Doctors—and sometimes nurses—don’t listen to us.

This is the only profession I know where even after passing an exam for licensure, you still have to prove your competence. Ever had a doctor write a prescription for a drug dose that does not exist and then argue with you about it? Or a nurse start counseling you, the medication expert, on medication administration? Honestly, I’ll take putting pills in sacks over this unwarranted drama any day.

6. People blame us for high drug prices.

Some patients (and even some doctors) seem to think pharmacists are running some sort of black market operation where we set prescription prices while pocketing imaginary enormous profits. I had a physician once tell me that pharmacists’ greed was the motive behind our pushing for provider status and prescriptive authority. Huh? Since profits in community pharmacy are steadily shrinking, you’re more likely to see us combing through couch cushions for pennies to keep the lights on—not being chauffeured to work in a Rolls-Royce.

7. We’re never really in charge—even when our title suggests otherwise (looking at you, Pharmacist-in-Charge).

Yep, even when we “run” stuff, we always answer to somebody. The director of pharmacy at a hospital often reports to the chief clinical officer. You can probably name many doctors and nurses who have climbed the ladder rungs to CEO, but try naming just one pharmacist-CEO outside of the heads of big box pharmacies or pharmacy associations. Sure, there are exceptions, but pharmacist representation in leadership is lacking.

8. Our pictures somehow always land on the 6 o’clock News and the FBI’s most wanted listed as the “Pharmacist Who Screwed Up.”

Medical errors are never a laughing matter, and even though we may not have written the prescription and cannot physically prevent a patient from taking more or less than the prescribed amount, we still bear the medication gatekeeper’s burden. My advice? Stay camera ready—just in case.

Frieda Wiley, PharmD, BCGP, is a writer in the Cincinnati, OH, area.
hen a 71-year-old woman left the hospital after being treated for uncontrolled hypertension and acute kidney injury, her medication list included prescriptions for amlodipine (Norvasc), metoprolol, and doxazosin.

Over the next few months, the woman’s health continued to decline and she experienced fatigue, personality changes, and a “stoic” facial expression. She returned to the hospital several times and underwent an angioplasty after complaining of chest pain.

On her third trip to the emergency room, she was described as having a shuffling gait and bradykinesia. Her creatinine levels were elevated, but medical professionals could not determine the cause of her symptoms until a medication reconciliation revealed she’d been mistakenly given the antipsychotic Navane rather than Norvasc at her outpatient pharmacy three months earlier.

It was a mistake that caused significant negative health effects and was chronicled in a 2016 Journal of Community Hospital Internal Medicine Perspectives article.

Experts say this isn’t an isolated incident.

Medical errors of all kinds, including medication errors, are now the third highest cause of death in the United States and may be responsible for 10% of all deaths in the country, according to a 2016 study by Johns Hopkins Medicine. According to the National Academy of Medicine, preventable medication errors harm 1.5 million Americans annually and cost hospitals an additional $3.5 billion each year.

“I think the problem is becoming worse because this is a complex medical system that we have,” says Deborah A. Pasko, PharmD, MHA, senior director of medication safety and quality for ASHP.
Strategies to prevent medication errors in recent years include a move to electronic prescribing and adding barcodes to drug products. But experts say these efforts have not eliminated the need for vigilance among pharmacists, technicians, and other healthcare professionals in the community and hospital setting. Here’s more on the actions pharmacists need to take to avoid some of the most common medication errors.

**Processing Errors**

In busy community pharmacy settings, the most common errors are related to processing more than one prescription in a confined space, Drug Topics Editorial Advisor Michael R. Cohen, RPh, MS, FASHP, president of the Institute for Safe Medication Practices (ISMP), says. ISMP is devoted to improving medication safety and runs a voluntary practitioner medication-error reporting program.

“They put one patient’s prescription in another patient’s prescription, and then once it’s in the bag, they often will seal the bag,” Cohen says. The patient is sent home with the wrong medication and may not realize it. “It’s a very common thing when people come home with someone else’s bag due to this type of mix-up,” he says. “Usually it’s because [pharmacists] are working quickly.”

Cohen says the error can be avoided by leaving the prescription out of a bag until the patient arrives to pick up the medication.

The Medicine Shoppe in Two Rivers, WI, goes one step further. It performs a “show and tell” on every prescription. Drug Topics Editorial Advisor Marvin Moore, PharmD, owner of the pharmacy, says during patient counseling sessions they actually open up the bottle, pour some of the pills out onto the counter, and show them to the patient. This not only ensures the patient has the right prescription before they leave the pharmacy, but also opens up a dialogue between the patient and pharmacist.

“There are opportunities to catch things where the patient will say, ‘Oh, that was supposed to be changed,’ or, ‘I am supposed to take two a day now instead of one?’” Moore says.

If a potential error is noted, pharmacists contact the prescribing physician to verify any prescription orders.

**Dosage Errors**

Electronic prescriptions were introduced to reduce medication errors and have been said to increase adherence to first fill medications since their introduction. In recent years, electronic prescribing systems have been embraced by most prescribers in the United States. According to a 2017 report from SureScripts, 77% of all prescriptions in 2017 were delivered electronically.

But while experts say it’s been a move in the right direction, electronic prescribing hasn’t eliminated medication errors. Electronic systems just pose different types of error-related problems, says Carter High, PharmD, director of legislative affairs for Best Value Pharmacies in Texas. “The downside is they are only as good as the people who put in the information on the other side.”

Cohen says common errors include selecting the wrong item from the computer screen.

Moore says electronic prescribing can also introduce confusing or conflicting instructions in the patient directions, or Sig (signature/label). “We also get a lot of prescriptions where they will pick a drug and a strength, and then in the Sig they’ll have a different strength,” he says.

To avoid this type of error, Moore’s staff looks back at previous prescription data for a patient and follows up if there has been a change, if there’s not a note that says dose decrease or dose increase, then we call to verify, because you just don’t know.”

**The Price of Errors**

<table>
<thead>
<tr>
<th>1.5 million</th>
<th>The number of Americans harmed by preventable medication errors annually.</th>
</tr>
</thead>
<tbody>
<tr>
<td>$3.5 billion</td>
<td>The amount of extra hospital spending caused by preventable medication errors annually.</td>
</tr>
</tbody>
</table>

1 The number of medication errors a hospital patient is subjected to daily.

Source: National Academy of Medicine
are any dose changes or other significant alterations to a prescription.

“We make a lot of calls during the day to prescribers’ offices to clarify,” he says. “Basically anytime we see a change, if there’s not a note that says dose decrease or dose increase, then we call to verify, because you just don’t know. We’d rather be on the safe side and pester the nurse a little bit versus hand out the wrong strength.”

Best Value Pharmacies has implemented a six-point check that requires technicians and pharmacists to verify the patient’s name, drug name, strength, directions, quantity, and doctor for each prescription they fill to reduce errors. Walgreens has also instituted a multistep prescription filling process with numerous safety checks built in to reduce human error, says Tasha Polster, RPh, vice president of Pharmacy Quality, Compliance, and Patient Safety. “We continually evaluate ways to enhance our operations, technology, and training to help improve healthcare delivery and promote a culture of continuous quality improvement.”

Care Transition Errors

Another common time for medication errors is during transitions of care when patients move to different types of settings, such as the hospital to home, or from a rehabilitation facility to a long-term care center.

“The more steps we build in and the more transitions of care we have, unfortunately, it brings to light broken systems and where things could happen,” Pasko says. This can be particularly problematic for insulin prescriptions, as there is no longer a standard concentration in insulin products. Many hospitals may only carry certain types of insulin on their formularies or may use a different concentration than the patient uses as an outpatient. This can create potentially dangerous situations.

Pasko says pharmacists should always be involved in transitions of care if possible. If a patient is being seen in an outpatient setting, Pasko, who used to work in a pediatric intensive care unit, says pharmacists need be proactive and ask patients questions such as whether any of their medications seem different, whether they look the same, and what time of day they are taking medications. “If a patient comes to me and says, ‘At home I was taking it and it was peach and round and now it is green and oblong,’ that would prompt me to just take a step back and verify that’s the right thing,” she says.

Given the increased chance of a medication error during a transition in care, Moore says his pharmacists typically do a medication reconciliation for anyone recently transitioning from one care setting to another.

Alert Fatigue Errors

Alerts are designed to warn healthcare providers about potential allergies, adverse reactions, or other health concerns, but they also bombard busy healthcare providers with information that may not be clinically relevant.

The result is that these alerts can be overridden or ignored. According to one 2013 study published in *PLOS One* that examined providers’ habits for drug-drug interaction warnings, more than 30% of alert overrides were considered inappropriate and subsequently put patients at increased risk for adverse events. “That is a very, very common problem where people just hit the return
key when they see an alert up on the screen,” says Cohen, who is also cochair of an allergy alert subcommittee for the National Information Technology Collaborative.

He points to a recently reported case in which a woman’s health history included information that she was allergic to fluoroquinolones. Yet, when she developed a urinary tract infection, a resident in the emergency room placed a verbal order for Levaquin. The nurse processed the order, as well as the pharmacy, never noticing the system alert to the allergy. They were about to administer the drug, when the woman told them of her allergy and refused to take it.

Other Errors
Medication errors also occur when pharmacies or electronic prescribers confuse similar sounding drug names. Tall man lettering, or capitalizing unique portion of a name, was designed to reduce these types of errors, but Cohen believes it isn’t fully being utilized.

He says the FDA has required manufacturers to use tall man letter for 20 name pairs but says ISMP believes this list should be expanded. The strategy would be more effective if the differences in drug names were highlighted by more than just capital letters, he adds.

“What we need to do is enlarge the font, not just with capital letters, but twice the size,” he says. “We need to bold those letter characters, we need to italicize them, we need to put background on them so they shout out to you: This is different.”

Other errors occur when pharmacists try to work too quickly or select the wrong containers. For instance, a pharmacist loading three containers into an automated dispensing machine may scan the barcode on one of the containers three times rather than scanning each one separately.

An effective strategy to preventing these type of errors is improving communication within the pharmacy and with patients.

High, who also serves as the operating manager for Best Value Rhino Pharmacy in Texas, holds monthly meetings to discuss potential errors that he caught before they left the pharmacy, using the meeting as a chance for his staff to learn.

“The feedback has worked really well,” he says, adding that in the last nine months that he’s been holding the meetings, the number of potential errors has been reduced by 70%.

Cohen says pharmacists also need to make a more concerted effort to talk with patients when a prescription is filled, particularly for high-alert drugs such as anticoagulants or insulins.

Technology on the Horizon
Technology can also be a critical aspect of reducing medication errors that can occur throughout the medication use cycle, such as barcode scanning, integrated electronic health orders, and tools such as smart infusion pumps.

“We really see the organizations that are moving the needle are the ones that have truly integrated electronic systems, which many still do not,” Pasko says of hospital settings.

Mark Neuenschwander, president of The Neuenschwander Company, which promotes sound deployment of medication-use automation, says bedside barcoding in hospitals is now nearly universal. It’s effective and reduces errors, as long as it’s used correctly. “If somebody gives the medication and then scans later, that’s like not putting your seat belt on until you are on the highway,” he says.

Neuenschwander is also a proponent of technology used to prepare medications that have to be reconstituted or remixed at a hospital.

“Liquids are high risk. So, we can use the same technologies in the clean room as we use at the bedside,” he says. This includes an automated check list of the recipe, product verification tools that use barcoding, and volume verification that must meet all the requirements before a label and barcode can be made.

Only about 20% of hospitals currently use this type of technology, and may not use it for everything, but he hopes it will become more widespread, says Neuenschwander, a Drug Topics editorial advisor. “I am not going to rest until we have universal adoption of preparation technologies for compounding,” he says.

Jill Sederstrom is a contributing editor.
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.

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.

INDICATIONS AND USAGE

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

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

Important Limitations of Use:

• Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.

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

CONTRAINDICATIONS

Hypersensitivity to vancomycin

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.

• Ototoxicity 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 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%).

Table 1: Common (≥5%) Adverse Reactions* for Vancomycin Hydrochloride Reported in Clinical 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 (%) (N=260)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Flatulence</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Edema peripheral</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<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:

Otototoxicity: 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 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

841 Woburn St. Wilmington, MA 01887 USA

Rev. 2/2018
A gender disconnect persists between pharmacy school graduates and independent pharmacy owners. More than half of pharmacy students in 2017 were women, 52.6%, according to the American Association of Colleges of Pharmacy. Yet only a handful of independent pharmacy owners are female.

“We have more women graduating from pharmacy school than we do men,” says Jennifer Zilka, group vice president of Good Neighbor Pharmacy’s Field Programs and Services. “Yet when you step into the community pharmacy market, less than 30% of owners are females. So, how do we pave the way for those future female business owners to learn about the benefits of owning a community pharmacy?”

Zilka moderated a panel discussion on “Women in Pharmacy” at ThoughtSpot 2018, Good Neighbor Pharmacy’s annual trade show.

Panelist Deidre Myers, PharmD, pharmacist and pharmaceutics laboratory instructor at Ohio Northern University, followed in her father’s footsteps. He owned a pharmacy. She is part owner of Harry’s Pharmacy in Carey, OH.

“Pharmacy isn’t just a job. When I worked in hospital pharmacy, I saw patients for a day or two and never knew the impact my recommendations had. As an independent, I see patients long term. I know what my recommendations mean for my patients,” she says.

Melynda Munden, PharmD, owner of Hemmingsen Drug Store in Marshall, MI, discovered independent pharmacy by working in one. “Pharmacy school just doesn’t prepare you for the business side of being an independent owner,” she says.

Heidi Snyder, PharmD, bought Drug World Pharmacies, which serves three local communities north of New York City, from her father, who founded the group in 1975. “My dad brought me up to believe I could do anything,” she explains, “even owning a pharmacy.”

More awareness needed

As one pharmacy student explains, not all pharmacists share that belief. “It’s not really a thing to see a female as a pharmacy owner,” says Jessica Satterfield, a second-year student at the University of Iowa. “Just getting information out there that the possibility exists would help.”

Graduates also need to hear more from women who have successfully balanced ownership and family. “When I talk with students about pharmacy ownership, the elephant in the room is motherhood,” Myers says. The reality is that with the right support system, you can do both. You are the best person to create that support system for yourself and for other women.”

Balancing work and life wasn’t a question for Snyder. She took time off every school day to meet her two children when they got off the bus.

Work-life balance in other settings

Work-life balance is becoming more of a priority in most pharmacy environments. Kerri Okamura, PharmD, director of Pharmacy Operations for KTA Super Stores, a Hawaii-based grocery chain, for example, uses flexible scheduling to attract and keep talented staff.

“I am surrounded by a great team, all of them young women with young families,” she says. “If they need time to see a child’s performance or something else, I encourage them to schedule around that. Being a woman in pharmacy is only an imposition if you let it be.”

Fred Gebhart is a contributing editor.
Cisplatin or carboplatin? Prednisone or prednisolone? Similarities between many drug names are a source of continuing confusion and medication errors. One method to reduce this confusion is “tall man lettering,” using capital letters, or bold face, or another color, to distinguish the different parts of two similar drug names. Prednisone and prednisolone, for example.

In 2001, the FDA requested that makers of 16 generic drugs with look-alike names use tall man lettering on labeling, according to Michael Cohen, RPh, MS, FASHP, president of the Institute for Safe Medication Practices (ISMP). ISMP has a longer list of look-alike names that it recommends be given the tall man treatment, Cohen says.

But does using capitals or boldface really help differentiate look-alike names or preventing errors? No, says Bruce L. Lambert, PhD, director of the Center for Communication and Health and professor at Northwestern University School of Communication. “There is no evidence that tall man reduces the rate of drug confusion errors in a real clinical practice setting. None.”

And it is not just about labeling. Cohen says. Databases and electronic prescribing systems should be amended to use as many ways as possible to differentiate look-alike names.

One of advantage of tall man lettering is that it is inexpensive. Labels costs little, and making changes to databases might have some costs at first due to new programming, but not much, Cohen notes.

There are few downsides to using tall man lettering. The biggest, according to Lambert, is that it can confer a false sense of security that enough has been done. “Everyone’s doing tall man because it’s cheap and easy, but you’d better keep measuring your error rate, you’d better keep doing other things, because … if you’ve just implemented tall man, that’s not enough.”

Barcoding is one of the best ways to help keep from confusing two similarly named drugs, both Cohen and Lambert say. “So as long as the name is entered correctly, and the order is processed, the pharmacist is going to scan in the container and get an error message,” Cohen says.

Using indication alerts would also cut down on drug confusion, Lambert says. If the EHR alerts that a drug being prescribed does not match a patient’s disease or condition, it could prevent a patient from getting a vial of hydralazine rather than hydroxyzine, he says.

Valerie DeBenedette is managing editor of Drug Topics.

REFERENCES
Performance-Based Pharmacy Networks

More pharmacies are affected. Here’s why.

The success of performance-based retail pharmacy networks for Medicare Part D is prompting some PBMs to create similar networks for their commercial and Medicaid populations. At the core of these networks are incentives for pharmacies that demonstrate improvement in medication adherence for certain chronic conditions and increased engagement.

“These networks need to strike the right balance between cost and safety and can run the gamut of pay-for-performance to shared savings to risk-bearing models based on patient outcomes,” says Crystal Lennartz, PharmD, vice president, pharmacy performance for Health Mart Atlas, a pharmacy services administrative organization (PSAO) under the McKesson umbrella.

Lennartz attributes these networks to the advent of preferred benefit structures, with performance and more dollars tied to contracts to improve the health of beneficiaries within plans and ultimately, reduce overall healthcare costs.

She says the trend began in 2016, when PBMs introduced variable direct and indirect remuneration (DIR) fee rates, in which pharmacies and PSAOs could achieve a lowered DIR amount if they met performance metrics.

Lennartz indicates that DIR makes performance-based networks in Medicare more punitive than in other populations. “A pharmacy could lose money when processing a claim through Part D, which is often correlated with arbitrary performance measures,” she says.

In 2018, all of Health Mart Atlas’ more than 6,800 pharmacies are in some type of performance-based network, including DIR designs. Lennartz says 2,000 of its pharmacies are eligible to participate in the true incremental, pay-for-performance programs across 47 states—nearly doubling over 2017. Total dollars committed to the program also have nearly doubled since last year.

Express Scripts to Launch Commercial, Medicaid Networks

Jennifer Awsumb, senior director, network products, Express Scripts, agrees with Lennartz that the concept of performance-based networks isn’t new. The PBM is using its experience with value-based contracting in Medicare in 2017, and extending it to Medicaid and commercial populations. “We focused on Medicare initially because of Star Ratings and because our clients wanted solutions with pharmacy at the center,” she says. ExpressScripts is launching a 12-month pilot this fall, addressing pharmacy performance in its commercial and Medicaid populations. It is designed to optimize medication therapy management, improve adherence, and promote better outcomes. As many as 35,000 pharmacies, including national chains, grocery store pharmacies, and community pharmacies, will participate in the pilot.

These pharmacies will be able to track their own performance and identify gaps in care via a web portal, while plan sponsors select four therapy classes they feel need improvement in medication adherence, and use results to measure each pharmacy’s performance.

Pilot metrics are recognized by the Pharmacy Quality Alliance, some of which are similar to CMS Star Ratings measures, but are not identical. These measures are adherence to diabetes medications, and to renin angiotensin system antagonists for hypertension and heart failure.

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<th>PERFORMANCE-BASED PHARMACY CHALLENGES</th>
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<td>Nathan Ray, senior manager, West Monroe Healthcare Partners’ healthcare practice in Chicago, says one of the biggest challenges is ensuring expansion across all pharmacies instead of using narrow networks.</td>
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<td>Lack of standardization for metrics and transparency are a challenge for Lennartz. “Pharmacies are not always aware of which patients are filling or refilling their medications because they are not receiving sufficient information from payers and PBMs,” she says.</td>
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<td>Health Mart Atlas uses EQuIPP, a performance information management platform that provides dashboards that report scores and relevant benchmarks across the same key quality measures. Lennartz says the platform also supports multitier views of a pharmacy organization’s performance.</td>
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CONTINUED ON PAGE 26>
use of statins for diabetes patients.

Express Scripts chose proportion of drugs covered, or what percentage of days a patient has a medication for diabetes, high cholesterol, and hypertension; use of a controller versus a short-acting rescue inhaler; and opioid overlap with benzodiazepine for the commercial and Medicaid performance network that officially starts January 1, 2019. Like the pilot, it will include 35,000 pharmacies.

Awsumb says that the PBM deliberately chose only three metrics for the pilot and five for the 2019 network because pharmacies indicated that too many measures could become overwhelming.

Retailers in the network pilot and in the 2019 network will compete against each other, incentivizing them to improve their performance through relative assessment, rather than predefined benchmarks. The lowest performers will be penalized, but not based on a benchmark.

Prime Therapeutics Highlights Quality Improvement

Prime Therapeutics is seeing growth in adoption of performance-based networks by health plan clients and pharmacies who are looking to differentiate their plans, says Bretta Grinstein-ner, assistant vice president, network management, for the PBM.

Prime has 11 health plans using performance-based networks for Medicare related to disease-specific conditions and specialty drugs. It is expanding its system infrastructure to support commercial and Medicaid plans.

Prime’s quality program in Medicare uses metrics appropriate for the line of business and/or goals of each health plan, including measures such as adherence to oral diabetes, hypertension, autoimmune, and cholesterol medications; statin use in individuals with diabetes; high-risk medication dispensing; generic dispensing; and comprehensive medication review completion rates, says Grinsteinner.

The PBM plans to add adherence to antiretroviral medications and statin use in individuals with cardiovascular disease, along with building quality programs around HIV, specialty multiple sclerosis, and autoimmune disorders including rheumatoid arthritis.

Pharmacies are measured at the each location on a year-to-date score with three measurement periods and receive performance rating on a scale of 1 to 5 for each measurement period. Performance in the top two tiers earns incentives. Pharmacies that receive a rating in the middle tier can earn incentives if there has been improvement over the course of the year.

Grinsteinner anticipates that performance networks that enable health plans and pharmacies to improve outcomes and increase adherence will reduce hospitalizations and emergency visits, thus saving money. In Prime’s Medicare book of business from 2015 to 2017, adherence for performance-based network pharmacies improved by 3.7%, nearly twice as much as the non-performance-based network pharmacies, whose improvement increased by 1.9%, she says.

CVS Health Follows Suit

In fall 2017, CVS Health initiated a new 30,000 store, performance-based, pharmacy network. The network is designed to improve clinical outcomes and help lower costs for CVS Caremark PBM clients and their plan members, according to CVS spokesperson Christina Beck-er.

The performance network uses a value-based management approach to achieve improved outcomes through medication adherence for diabetes, hypertension, respiratory conditions, depression, and behavioral health. It also helps to provide cost savings through formulary compliance.

Savings will vary, but clients moving from a national network can expect to save up to 4% in gross pharmacy spending, Beckerman says. Pharmacies are encouraged to implement their own proprietary programs and work flow processes to achieve results, such as encouraging members to take their medications as instructed, improving overall health, and lowering costs for patients and pay-ers, not just dispensing medication.

“Across healthcare, we are seeing a shift away from fee-for-service to more value-based reimbursement and payment models,” Beckerman says. “In pharmacy care, we expect network design options that align incentives and outcomes to also grow as payers look for new ways to help contain costs and drive better health outcomes for their member populations.”
Epidiolex: Approved for Two Pediatric Epilepsy Syndromes

In June, the FDA approved cannabidiol oral solution (COS; Epidiolex, GW Pharmaceuticals) for treatment of seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS) in patients 2 years and older. LGS and DS are rare forms of severe epilepsy that emerge in early childhood. Patients often experience treatment-resistant seizures despite taking multiple antiseizure medications. COS is the first approved medication that contains a purified drug derived from marijuana, and the first approved drug for DS.

Efficacy

Approval of COS was based on data from three randomized double-blind placebo-controlled trials of 516 patients with either LGS or DS. Treatment with COS 20 mg/kg/day was tested in both LGS and DS patients (Studies 1, 2, and 3), and COS 10 mg/kg/day was tested in LGS patients (Study 2).

In LGS patients, COS was associated with a significant (p<0.01) reduction in total seizure frequency. The median percent reduction (per 28 days) was 41% in patients treated with 20 mg/kg/day versus 14% in placebo patients in Study 1 and 36% in the 10 mg/kg/day group, 38% in the 20 mg/kg/day group versus 18% in the placebo group in Study 2. Additionally, a greater improvement on the subject/caregiver global impression of change was reported in patients treated with COS compared with placebo in Studies 1 and 2.

In DS patients, COS was associated with a significant (p=0.01) reduction in total seizure frequency. The median percent reduction (per 28 days) was 39% in patients treated with COS 20 mg/kg/day versus 13% in placebo patients in Study 3.

Safety

The most common adverse effects (>10%) were elevated transaminases (16%), decreased appetite (22%), diarrhea (20%), somnolence (25%), fatigue (12%), insomnia (11%), infection (41%), and rash (13%).

COS caused dose-related elevations of liver transaminases (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]). The majority of ALT elevation occurred in patients also taking valproate, and to a lesser extent, clobazam. Patients with baseline transaminase elevation experienced higher rates of transaminase elevation while on COS. Obtain serum transaminases and total bilirubin levels prior to treatment initiation, and at 1, 3, and 6 months after initiation, as well as 1 month after dose change or addition/discontinuation of any drug that affects the liver. If a patient develops clinical signs or symptoms of hepatic dysfunction, interrupt or discontinue treatment.

As with most antiepileptic drugs, COS increases the risk of suicidal thoughts or behavior. Monitor patients for the emergence or worsening of depression or any unusual changes in mood or behavior.

COS should be withdrawn gradually to avoid increased seizure frequency and status epilepticus. No contraindications with COS are known other than hypersensitivity to any ingredient. Insufficient information exists on the risks of COS on a fetus or breastfeeding infant.

Dosing

The recommended starting dose of COS is 2.5 mg/kg twice daily (5 mg/kg/day). After 1 week, the dose can be increased to a maintenance dose of 5 mg/kg twice daily (10 mg/kg/day). If further seizure control is warranted, the dose can be increased to the maximum recommended maintenance dosage of 10 mg/kg twice daily (20 mg/kg/day). Dose adjustment is recommended for patients with moderate or severe hepatic impairment. Epidiolex is supplied as a 100 mL bottle of 100 mg/mL solution.

Ten Fast Facts About Shingles

More is known about shingles—and more can be done to help patients—than ever before.

Check out these important talking points about this serious condition below so that you can discuss them with your patients:

1. **Shingles is caused by varicella zoster, the same virus responsible for chickenpox.** After a chickenpox infection, the virus goes dormant in the nerve cells of the spine. A person’s immune system works to keep the virus under control, but if immunity is compromised, the virus can erupt out of the nerve root and form the painful rash known as shingles (herpes zoster).

2. **About one million cases of shingles are diagnosed in the United States annually,** with up to half of them in people over the age of 60. One in three people will develop shingles in their lifetime, and it may reactivate multiple times in some individuals.

3. **Although shingles is associated with aging and is typically more severe in those over the age of 50, anyone who has had chickenpox is at risk of developing shingles.** Anything that weakens a person’s immune system can lead to shingles, including certain medications, cancers, infections, or stress.

4. **Shingles is a painful infection of the nerve supplying an area of skin.** Nerves extend out of the spine in pairs, with one nerve going to each side of the body. That’s why a shingles rash presents on only one side and rarely crosses the midline of the body.

5. **Shingles shows up as fluid-filled blisters that form along the distinct bands of dermatomes, each of which corresponds to a single sensory nerve.** The rash is often preceded by several days of acute pain, aches, skin sensitivity, and fever.

6. **Patients diagnosed within 72 hours of developing the rash generally have a better outcome.** Antivirals—including acyclovir, famciclovir, and valacyclovir—are often prescribed to stop the spread of the virus. When started early, antivirals can shorten the pain and rash to a couple of weeks instead of a month.

7. **Steroids can help alleviate the pain associated with shingles,** which is often described as tingling, burning, itching, and numbness. Anti-inflammatory medications such as ibuprofen and naproxen, topical Benadryl ointment, or cool compresses of baking soda and water can also provide relief.

8. **The most common complication associated with shingles is postherpetic neuralgia (PHN), a form of chronic nerve pain.** It occurs in about one-fifth of all cases and is the result of nerve damage during the shingles outbreak. In people with impaired immune systems, complications from shingles can include pneumonia, brain inflammation, or even death. Other long-lasting effects are peripheral motor neuropathy, skin infection or scarring, transverse myelitis, eye problems, and general weakness.

9. **Shingles is contagious because the virus can spread to and infect a person who has never had chickenpox.** Until the blisters dry up and scab over, shingles patients are advised to avoid contact with children under the age of one, pregnant women, and immunocompromised individuals.

10. **Two shingles vaccines are available.** The newer one is Shingrix, a non-live recombinant vaccine given in two doses that was approved by the FDA in 2017. It has been proven to be more than 90% effective against shingles and also reduces the overall incidence of PHN. Shingrix is recommended by the CDC for healthy adults aged 50 and older. The older vaccine is Zostavax, which contains a weakened chickenpox virus and is recommended by the CDC for people 60 years old and older. Licensed by the FDA in 2006, it reduces the risk of developing shingles by 51% and PHN by 67%. Either vaccine can be given to people who have already had shingles to prevent another episode.

Beth Longware Duff is a contributing editor.
Pharmacists Step into Leadership Roles

When pharmacist David Angaran, MS, FCCP, FASHP, first set foot on the University of Wisconsin campus in Madison, WI, in 1968, the campus, including students and faculty, was filled with protestors, activists, and other impassioned individuals challenging the social, racial, and political dynamism that defined the era. Three years before, President Lyndon Johnson had signed the Medicare Act. The law pumped money into the healthcare system, and Angaran, who was pursuing a Master of Science in Hospital Pharmacy and Residency, believes the pharmacy world benefited from the act’s passage.

“It was a time when people began to question authority,” recalls Angaran of the evolving culture he says helped ignite the initial flames in the evolution of pharmacy leadership. “Pharmacists began questioning the dialogue in prescribing medications and having discussions that facilitated and gave permission to people who were very bright to fulfill leadership skills.”

Today, that questioning has manifested into a variety of leadership roles held by pharmacists, roles that were either previously nonexistent or traditionally held by nonpharmacist health professionals, namely physicians and nurses.

Now CEO of his own consulting firm, Communication Prescription, LLC, Angaran has held a variety of groundbreaking leadership roles, including overseeing medication therapy management programs, spearheading telepharmacy operations, and working in continuous improvement, while making a career-long commitment to pharmacy education.

Pharmacist Leaders in Action
Examples of pharmacist-trained leaders include Williams Evans, PharmD, former CEO at St. Jude Children’s Research Hospital; Michael Sanborn, MS, RPh, FACHE, president/CEO of Baylor Scott & White All Saints Medical Center–Fort Worth; and James Klauck, RPh, MS, FACHE, FASHP, senior vice president at Froedtert & the Medical College of Wisconsin, says James Hoffmann, PharmD, chief patient safety officer at St. Jude.

Pharmacists are also serving as leaders in supply-chain management, quality, and clinical professional services, which allow them to leverage their training and experience in various facets of the health system experience, says Hoffmann.

A big factor contributing to demand for pharmacist leaders is the growing recognition of pharmacists’ value, says James Jorgenson, RPh, MS, CEO of Visante, a health-systems compliance and managed care medication management company.

“The number one contributor to medical error is medication, and if you think about how medications are the fastest growing arm of healthcare, then pharmacy is an underutilized resource,” Jorgenson says. “So, if you really want to make an impact on healthcare, then engaging pharmacy is a logical solution.”

Advancement Tips
For pharmacists in interested in pursuing leadership positions, attaining specialized training and leveraging unique skill sets is a smart move.

Jorgensen, a Drug Topics editorial advisor who has served as a vice presi-
dent and chief pharmacy officer of Indiana’s largest state-based healthcare system and dean of a pharmacy school, pursued a dual master’s and hospital pharmacy residency program to expand his opportunities after spending a year in community practice.

Magaly Rodríguez de Bittner, PharmD, BCPS, CDE, FAPhA, also attained more specialized training to help her thrive in her role. After more than three decades of practice, the associate dean for clinical services and practice transformation at the University of Maryland began a fellowship in population health two years ago to better understand challenges in that area “from the leadership perspective.”

Rodríguez de Bittner’s additional educational efforts align with her work as executive director for Innovative Pharmacy Solutions at the university—a center that helps improve integration of pharmacists within the University of Maryland healthcare system in population management, using telepharmacy, disease state management, onsite pharmacist visits, and other services.

With his sights set on research, Hoffmann, enrolled in a masters’ program with a concentration in health services research that had an administrative residency and fellowship in outcomes research and drug policy interwoven into the program after earning his PharmD in 2001.

Hoffmann says his membership in Solutions for Patient Safety, an organization of more than 130 children’s hospitals, also enhanced his leadership skills when he transitioned from his role in medication safety to patient safety, by helping him quickly acquire industry-specific knowledge and identify critical issues.

Leadership Barriers
While awareness of pharmacist value is growing, many pharmacists interested in leadership roles still encounter barriers related to lack of knowledge regarding their abilities.

For Milap Nahata, MS, PharmD, director of the Institute of Therapeutic Innovations and Outcomes at Ohio State University, relentless persistence and optimism are two of the most critical elements to a career filled with numerous promotions and countless accolades. He recalls a situation in which many clinical journals rejected some of his initial publications because the idea of a pharmacist as the lead author was inconceivable at the time.

Instead of becoming discouraged, Nahata empathized with the editors. “Had I been in [the journal’s] position, I might have done the same thing,” he says. Undeterred, Nahata continued to submit his research to various clinical journals and eventually his publications were accepted.

Born in India, Nahata says his mother set an early example of leadership by maintaining an optimistic outlook on life despite adversity and hardship. Nahata’s mother did not have much education, and his father had to work away from home.

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JIM JORGENSEN, RPH

his role in medication safety to patient safety, by helping him quickly acquire industry-specific knowledge and identify critical issues.
Pharmacist as a Health Plan Director

BY KAREN APPOLD

Patrick Mitsch, PharmD, pharmacy director, UCare, was recently named a “Top 10 Up-and-Coming Industry Leader” by Drug Topics’ sister publication, Managed Healthcare Executive (MHE). The annual list is made up of pharmacists, doctors, health plan executives, and technology entrepreneurs in healthcare.

Mitsch received his doctor of pharmacy degree from the University of Minnesota in 2012. He worked as a retail pharmacy manager for CVS, then joined CVS Caremark in 2013 as a clinical pharmacist in its Medicare business unit. He came to UCare, a not-for-profit health plan, in 2015, and he quickly ascended to director of pharmacy in 2017. At UCare, Mitsch, now 31, uses his community experience to lead innovative quality programs that advance medication adherence and focus on preventive opioid management, cost containment, and member and provider education.

MITSCH TALKED WITH MITSCH ABOUT HIS ROLE:

MHE: Why did you choose your profession?
Mitsch: Growing up, I saw a pharmacist’s impact firsthand as my grandfather cared for my grandmother who had Alzheimer’s disease. This pharmacist always ensured that my grandfather had the necessary knowledge to manage my grandmother’s complex medication regimen. This experience led me to want to become a community pharmacist. After achieving this goal and being able to impact patient care on an individual level, I soon realized the benefits of influencing patient care on a population health level. As director of pharmacy at UCare, I can positively impact patient care for those communities and populations that need it most, including communities where I grew up and worked.

MHE: What has been your biggest learning experience?
Mitsch: Working for a health plan that serves many underserved populations has taught me that we need to have a holistic view when approaching patient care. For example, if we want to drive medication adherence for these members, we need to meet them where they are and understand the cultural, economic, and social issues that may be barriers.

MHE: What change would you like to see in healthcare in the next 10 years?
Mitsch: I would like to see the opioid epidemic become a thing of the past. This nationwide crisis requires engagement from all stakeholders to drive the kind of change needed to end this epidemic. Health plans play a significant role in this process and we must collaborate with, educate, and empower patients, providers, and the communities we serve.

This is an excerpt from an article that originally ran in Managed Healthcare Executive, Drug Topics’ sister publication.
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Proposed Law Could Change Drug Pricing

Although the act would not prohibit manufacturers from increasing prices, it could change things. Here’s why.

A proposed new law addresses the rising prices of pharmaceutical drugs by requiring price transparency. The law, the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, would require drug manufacturers to notify HHS and submit a transparency and justification report 30 days before they increase the price of certain drugs by more than 10% over one year or more than 25% over three years.

Manufacturers would need to justify each price increase for a qualifying drug, and report its manufacturing, research and development costs; net profits; marketing and advertising spending; and other information.

Although the act would not prohibit manufacturers from increasing prices, it would give consumers notice of price increases and bring transparency to the market for prescription drugs for the first time.

In July, Rep. Francis Rooney (R-FL) became a cosponsor of a bill supporting the FAIR Drug Pricing Act, making it bipartisan in the House and Senate and giving it momentum. The bill still needs to be considered by House and Senate committees before coming to a vote in both chambers. “The House and Senate will need to reconcile and agree on any discrepancies before the bill goes to President Trump to sign,” says Joseph Honcz, RPh, MBA, vice president of Payer Access Solutions, Precision for Value, a healthcare consulting company.

Industry experts have varying opinions on how the act could affect drug prices. Here’s are three possible outcomes.

1. It might deter huge drug price increases.
The act proposes public shaming drug manufacturers that increase their drug prices greatly. The paperwork that companies file paperwork with HHS would be public. “None of this limits price increases, it only requires more public disclosure of increases,” says Stacie Dusetzina, PhD, associate professor of health policy, Vanderbilt University School of Medicine, Nashville, TN. “But companies may rethink increasing prices if filing these reports is time consuming or would create significant public backlash.”

Jodie Thellin Skyberg, global pharmacy and pharmacy benefit manager practice leader at Cognizant, a technology and consulting services company, says the new legislation might discourage pharmaceutical companies from raising prices dramatically, given the public exposure of the reported information and negative impact to a company’s brand. “At a minimum, it will cause drug companies to reconsider price increases by having to disclose actual costs versus revenue and justify increases,” she says.

2. It could increase drug prices.
While the act may cause pharmaceutical companies to think more about price increases, Sharon K. Jhawar, PharmD, MBA, BCGP, chief pharmacy officer, SCAN Health Plan, a health insurer in Long Beach, CA, believes drug companies will find ways to work around it.

Companies could limit increases to 9.9% or 24.9% to avoid notifying HHS. The bill is somewhat vague on the one- and three-year periods, she says.

“It may have an unintended consequence of manufacturers setting even higher list prices when a medication first launches on the market,” Jhawar says.

Dusetzina says the act could result in drug companies using limits on drug price increases to justify even higher initial prices.

3. It might have minimal impact.
The notification requirement might lead drug manufacturers to increase drug prices less frequently, says Honcz. “However, this might only be temporary until drug companies better define the process and become comfortable with it,” he says.

Karen Appold is a medical writer in Lehigh Valley, PA.

“The at a minimum, it will cause drug companies to reconsider price increases by having to disclose actual costs versus revenue and justify increases.” Jodie Thellin Skyberg
Technology to Treat Chronic Pain

New devices might help curb the need for opioid prescriptions

Up to 30% of patients prescribed opioids for pain misuse them, according to the National Institute on Drug Abuse (NIDA), a division of the National Institutes of Health. Between 8% and 12% of patients who are prescribed opioids develop an addiction. In total, the institute states that 115 people in the United States die every day due to opioid overdoses.

“Given the nationwide emphasis on the opioid crisis, those living with chronic pain feel there is a stigma that comes with seeking out strong pain prescriptions,” says Shai Gozani, MD, PhD, president, CEO, and director of NeuroMetrix, Inc., the company that created Quell, a wearable neurostimulation device. “It’s important to provide individuals with long-term pain conditions with enough options to be able to find an effective relief system that works for them.”

“Because pain is extremely personal and is experienced differently by all people, those living with chronic pain often need a variety of treatments to find relief—what we call a ‘toolbox approach’ to chronic pain,” Gozani says.

Below are some technology solutions on the market that can treat chronic pain, allowing patients to eliminate or decrease their dependence on opioid drugs.

Quell by NeuroMetrix
By using neurostimulation technology to tap into the body’s natural pain response and block pain signals, Quell helps patients with chronic back, arthritic, nerve, leg, and foot pain. The wearable device is FDA-cleared for daytime and overnight use. It is inserted in a cuff that can be positioned on the body and has an accompanying app that helps people track pain management and sleep patterns affected by chronic pain.

A clinical study of 713 Quell users published in the Journal of Pain Research in April found that 80% reported improvement in their chronic pain levels and about 66% reported reduction in their pain medication use by using Quell. On average, study participants used Quell for 35 hours per week.

SPRINT PNS system by SPR Therapeutics
The SPRINT PNS system is designed to treat pain through peripheral nerve stimulation (PNS). The single thread-like wire, or lead, is implanted through a needle introducer under ultrasound guidance and is placed approximately 1 cm from nerves. It can deliver percutaneous stimulation therapy for up to 60 days.

The system can be used to treat post-amputation, lower back, shoulder, and knee replacement pain.

“As a device there are no withdrawal symptoms, and consequently, no drug-related side effects,” says Mark Stultz, senior vice president of market development for SPR Therapeutics, the makers of the system. “SPRINT is intended to provide pain relief directly to the nerve, where it is needed, whereas opioids are systematic, have significant side effects, and are susceptible to addiction and diversion.”

The system is on the market, and the company has launched its next generation, the SPRINT extensa PNS system, a dual lead system that allows for more thorough coverage of the pain area. This dual-lead system received FDA approval on July 31.

BreatheVR by Neon
Virtual reality (VR) is a simulation of a three-dimensional image or environment with which a user can interact using a headset and other equipment.

“It’s important to provide individuals with long-term pain conditions with enough options to be able to find an effective relief system that works for them.”

SHAI GOZANI, MD, PhD
VR can provide a unique approach to pain management, as studies show that immersive distraction can de-escalate some chronic pain.

BreatheVR is an application available through Samsung Gear VR and Oculus Go headsets that helps patients by guiding them through deep breathing and meditation exercises to alleviate pain.

The BreatheVR application engages users in a virtual animated meadow, and has them listen to music and bird songs. The user is asked to inhale and exhale, and as their breath is detected by the headset’s microphone, the leaves in the virtual reality environment move. This sequence is then repeated, encouraging the user to get into a pattern of diaphragmatic breathing.

Deepa Mann-Kler, founder and CEO of Neon, says a 2017 pilot study of BreatheVR found that in less than three minutes, 80% of participants reported a de-escalation of pain.

“The biggest drop in pain was 50%, from 7 to 3.5 on the visual analog psychometric response pain scale,” Mann-Kler says. “The benefits of deep breathing and meditation have long been recognized as aiding relaxation. Recent studies using virtual reality also evidence further benefits. BreatheVR combines the power of virtual reality and deep breathing to create a uniquely immersive user experience.”

Mann-Kler says there are more than 100 active users of the application and the company is compiling use cases from fibromyalgia patients who are using BreatheVR at home.

“We have not fully explored VR’s capabilities yet,” Mann-Kler says. “When we can truly personalize the experience for each person through the use of full sensory and biodata feedback loops, we will actually be meeting each person’s needs on an individual basis.”

StimRouter by Bioness

This long-term pain solution treats chronic nerve pain through peripheral nerve stimulation. It has been used on 24 different peripheral nerves since launching in 2016. The device is 15 cm long and “feels like a limp piece of spaghetti,” says Mark Geiger, global director of marketing implantables at Bioness, the company that produces StimRouter.

The StimRouter is implanted through the skin, while the patient is under local anesthesia. According to Geiger, patients can provide feedback to the physician who is implanting the device immediately.

“By stimulating the target peripheral nerve with a small amount of energy that feels like a gentle tingling sensation, the nerve cannot communicate a pain signal. Over time, this stimulation may cause the nerve to perform more normally,” Geiger says. “So, the difference is targeted pain management at the source of the pain compared to global pain reduction with an oral or IV pain medication with all the typical, sometimes deleterious side effects.”

“The StimRouter is a permanent solution meant to last a lifetime. In many cases, based on many hundreds of devices already implanted, patients use the StimRouter for shorter durations over time with increasing carry-over pain relief, meaning the pain relief lasts for hours/days after the StimRouter is shut off by the patient,” Geiger says.

Donna Marbury is a writer in Columbus, OH.
Can Mylan and the FDA Solve the EpiPen War?

Faced with shortages and high prices, Mylan and the drug agency are taking steps to increase patient access.

After a year filled with public outcry over pricing and drug shortages, the FDA and Mylan are taking steps to increase patient access to epinephrine auto-injectors, notably the EpiPen.

Mylan’s manufacturing partner, Meridian Medical Technologies (a subsidiary of Pfizer), continues to experience interruptions in the production of EpiPen and EpiPen Jr Auto-Injectors, according to Mylan. The company says it is “actively exploring several options” to help fix the supply problem, adding that its priority is to ensure that patients with life-threatening allergies have access to EpiPens.

Mylan is promising to expedite shipments from Pfizer and to maintain closer contact with it and with authorities about the status of EpiPen shipments.

The FDA, meanwhile, extended the expiration date of specific lots of 0.3 mg EpiPen products marketed by Mylan by four months beyond the labeled expiration date.

“FDA continues to work closely with Mylan on EpiPen production and supply, and also has been in contact with the other manufacturers of epinephrine auto-injectors, including Adrenaclick and Auvi-Q, regarding their supply as the school year begins since this is historically accompanied by increased product demand,” the agency said in a statement.

Generic Approved

The FDA made another big move in August, approving the first generic versions of EpiPen and EpiPen Jr. Teva gained approval to market its generic epinephrine auto-injector in 0.3 mg and 0.15 mg strengths.

“Having more than one source of product for an emergency situation remains important in the U.S. market given the history of shortages as well as price,” says Randy Vogenberg, PhD, principal, Institute for Integrated Healthcare and chairperson of the Employer-Provider Interface Council.

While Teva did not reveal the cost of its generic auto-injector or when it will be available, in a statement the pharmaceutical manufacturer said it is applying its full resources to this launch in the coming months and is eager to begin supplying the market.

“I think watching the cost of the generic as it becomes available will be more important and interesting, even more so, if it becomes available during shortage conditions,” says Nicholas W. Carris, PharmD, assistant professor, University of South Florida College of Pharmacy and Morsani College of Medicine.

FDA Commissioner Scott Gottlieb, MD, in a statement said the approval of the first generic version of the most-widely prescribed epinephrine auto-injector in the United States is “part of our longstanding commitment” to safe low-cost generic options. “This approval means patients living with severe allergies who require constant access to life-saving epinephrine should have a lower-cost option, as well as another approved product to help protect against potential drug shortages,” he added.

The FDA also said there are “authorized generic” versions of EpiPen and Adrenaclick, which are marketed without the brand names. An authorized generic is made under the brand name’s existing new drug application using the same formulation, process, and manufacturing facilities that are used by the brand name manufacturer.

“Families and healthcare entities have been held hostage to product shortages in many critical care conditions, so these FDA efforts are welcome,” says Vogenberg. “Allowing competition to occur should help to further lower product prices at the patient level along with purchasers of care through commercial plans and CMS.”

 Having more than one source of product for an emergency situation remains important in the U.S. market given the history of shortages as well as price.”

—RANDY VOGENBERG, PHD

Christine Blank is a contributing editor.
In February, the DEA Office of Diversion Control moved to revoke a Florida pharmacy’s certificate of registration, a decision that should make pharmacists take notice.1,2 This decision can educate pharmacists and technicians on what to do before the Feds enter the pharmacy.

Trinity Pharmacy II is a full-service family-owned independent pharmacy in Clearwater, FL, that specializes in compounding.1,2 In February 2018, the DEA Office of Diversion Control published an Order to Show Cause proposing revocation of Trinity II’s DEA Certificate of Registration for its Clearwater location, alleging that the pharmacy’s “continued registration is inconsistent with the public interest.”1

The DEA’s order set forth several reasons,1 saying that Trinity II failed to comply with federal controlled substance law and dispensed controlled substances outside the usual course of pharmacy practice. The order alleged it ignored red flags and dispensed prescriptions without resolving those red flags. In addition, the DEA alleged the pharmacy, on at least one occasion, dispensed “a Schedule II controlled substance outside the usual course of professional practice . . . and in contravention of its corresponding responsibility.”1

Andrew Hull wrote an article in FDA Law Blog noting Trinity II was “a must-read for any pharmacy registrant or their counsel.”3 The DEA revoked one pharmacy controlled substance license in 2017, but by mid-2018, has revoked four, including Trinity II, he says.3 Of particular note is the DEA’s discussion of the pharmacy’s scienter, or knowledge of wrongdoing, often referred to as intent. In particular, the hearing officer looked at the concept of “willful blindness,” ignoring what was in plain sight.

An important government witness was its pharmacy expert who testified extensively regarding red flags.1 A red flag is anything “that might indicate or suggest that prescriptions were filled outside the usual course of pharmacy practice,” he said in testimony. A red flag could be indicative of abuse or misuse, over or under compliance, drug-drug interactions, or a “forged or altered prescription.”1

Such issues would be reviewed and resolved by a pharmacist “before filling any prescription” as part of the “prospective drug use review,” the testimony states. The pharmacist’s resolution of these red flags “would be documented on the face of the prescription, on the rear of the prescription, or in the patient profile.” The standard of practice regarding such documentation is that it has to include a reason that makes sense to the average pharmacist and that the prescription is legitimate despite the red flag(s). In other words: “If it’s not written down, you didn’t do it.”1

When I used to defend criminal cases, I occasionally hired a particularly good private detective. He had a favorite saying: “The faintest ink is sharper than the keenest memory.” Every pharmacist and technician should read the Trinity II decision.1 They should look closely at the discussion of red flags, the expert testimony about prospective drug review, and the need to document information surrounding red flags. The government has used this testimony repeatedly when charging pharmacists and pharmacies with illegally dispensing controlled substances. Do not overlook the need and concept of a pharmacist’s corresponding responsibility. If you fail to abide by these lessons, you may be charged with filling illegal prescriptions knowingly and with willful blindness. Protect yourself—document red flags and how you resolved them.4


KEN BAKER is a pharmacist and an attorney. He teaches at Midwestern University, Glendale, AZ, and at the University of Florida. He consults in the areas of pharmacy error reduction, communication, and risk management. Baker consults with Pharmacists Mutual Insurance Company. He is an attorney, of counsel, with the Phoenix law firm Renaud Cook Drury Mesanos, PA. Contact Ken Baker at ken@kenbakerconsulting.com.
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MARKETPLACE CAN WORK FOR YOU!
I tell my technicians that I am the only one in the pharmacy who can make a mistake. It’s my responsibility to catch any discrepancy between the provider’s order and what the patient receives. If a patient receives a prescription that is in error, it is my fault.

Back in August 2016 I wrote a column describing my “red pen” technique. In that essay I described how I physically check prescriptions using a red pen, so I know I verified that prescription. I make every effort I can to ensure the accuracy of every order.

A sad event occurred in our area. A patient had a prescription filled for amitriptyline 10 mg at her local pharmacy. When she got the prescription refilled at the same store, the pills looked different. She called the pharmacy and the tech reassured her that “these generics change all the time.”

A few days later, before she started the new batch of pills, she again called the pharmacy and the same tech reassured her that the generics are always changing. The patient started the new bottle, and after a couple of days, had slurred speech and was disoriented and blamed the pills. Finally, her daughter took her to the hospital, where everyone assumed the pills were correct.

It took a young family member to look up the medication on a database to learn that it was amitriptyline 100 mg pills in the bottle. The outcome was not good. The patient had a mild stroke attributed to the tenfold increase dispensed in error.

The pharmacy had two opportunities to verify the prescription, as did two healthcare professionals in the hospital. No one did.

Because of situations like this, my rule is that when a patient inquires because of a different appearance in their medication, I am the only one who will make such a verification. We use a barcoded pill counter, I use my red pen, but ultimately, I get on the phone after physically verifying the medication. I’ll get the meds off the shelf or pull up images on a database; and only I will talk to the patient.

Since I never elucidate a problem without a proposed solution, and given the fact that I do everything I can in my pharmacy to minimize errors, I’d like to enlist the help of the FDA in the name of patient safety.

Here is my proposal: We need standardization.

“...we need standardization...”

When I need a bolt and nut for a home project, it doesn’t matter which hardware store I go to. If I need a #3 bolt with a coarse thread I can be assured there will be 48 threads per inch due to standardization.

I’d like to see the FDA adopt the standardization our hardware manufacturers use.

When any abbreviated new drug application is approved, there should be in that approval letter exactly what the tablet or capsule looks like. I feel all generics of a drug should be the same size, color, and shape. One side should have three or four letters for the generic name, plus the strength; for example, Omep 40 for generic omeprazole (Prilosec) 40 mg. The other side should have the manufacturer’s identifying marks.

For a drug like levothyroxine, where there is a question of bioequivalence between generics and brands, different generics could keep different shapes or colors to alert patients that a switch has been made. But this would be the exception to the rule.

When a patient gets a prescription for lisinopril 20 mg, will they receive a round white tablet, a pink round tablet, an oblong pink tablet, or a white pentagonal tablet? It depends on the manufacturer. Even us experienced pharmacists must check a database to verify whether it is lisinopril.

Standardized markings would enable anyone to verify the name, strength, and manufacturer of a tablet. Patients would not be so confused as to what color and shape their meds are, as the pills would be the same.

I’m asking no more from the FDA than I am from the suppliers of my hardware store.  

PETE KRECKEL, BSPharm, practices independent community pharmacy in Altoona, PA. He welcomes your e-mails at pharmcanoe@aol.com
OPHTHALMIC NSAID PRESCRIPTION FULFILLMENT
A ROUNDTABLE DISCUSSION | MAY 15, 2018

INTRODUCTION
On May 15, 2018, a roundtable of pharmacists was convened to discuss prescription fulfillment of nonsteroidal anti-inflammatory drugs (NSAIDs) for cataract surgery. To gather varied perspectives, pharmacists from 5 US states* participated in a robust discussion about the role of ophthalmic NSAIDs in cataract surgery, one surgeon’s clinical rationale for choosing specific ophthalmic NSAIDs, reasons for substitutions of ophthalmic NSAIDs at the pharmacy, and best practices for ensuring fulfillment of ophthalmic NSAIDs as prescribed, including the importance of building relationships between ophthalmic surgeons and their local pharmacists.

In addition to geographical diversity, the participants came from a diverse group of pharmacies in terms of size, number of locations, customer demographics, length of time in practice, and pharmacy type (independent or part of a chain). All of the participating pharmacists have had experience filling prescriptions for NSAIDs after cataract surgery.

The discussion was moderated by ophthalmologist Inder Paul Singh, MD, of the Eye Centers of Racine & Kenosha, Wisconsin.

As part of his commitment to advancing the field of ophthalmology, Dr. Singh has developed innovative ways to ensure that his patients receive the medications he prescribes—by educating them about his rationale for medication selection and by building relationships with pharmacists, whom he views as an integral part of the cataract care team along with physicians’ assistants, nurses, technicians, and ophthalmic optometrists.

THE ROLE OF NSAIDS IN CATARACT SURGERY
The incidence of cataract surgery has steadily increased over the past 3 decades, as has second-eye surgery.1 Age-related cataract affects more than 22 million people in the US, and that number is expected to rise to 30 million by 2020.2 The prevalence of cataract exacts a heavy toll on patients, the health care system, and society as a whole. Direct medical costs alone for cataract treatment—that is, not counting the indirect costs of time off from work and lost productivity—are estimated at $6.8 billion annually.3

The roundtable participants were not surprised by these statistics, as many of them see a high volume of cataract patients. One pharmacist noted that he saw approximately 400 cataract surgery patients in 2017; another saw more than 600.

In addition to treating an increasing number of cataract patients each year, Dr. Singh sees younger cataract patients than he once did. “I’m not only treating 70- and 80-year-olds, but a lot of 50- and 60-year-olds,” he said. These younger patients, in Dr. Singh’s experience, have higher expectations than older patients. “New patients often hear from their friends how good their post-cataract vision is and how easy the recovery process was, and they want the same for themselves,” he said. “Managing my patients’ ocular comfort needs after cataract surgery is critical. Patients often judge the quality of their surgery—and my skill as a surgeon—by the amount of post-surgical pain they experience.”

Cataract surgery, however, causes physical trauma to the eye, which disrupts the blood-aqueous barrier and releases inflammatory mediators, including prostaglandins and leukotrienes.4 Post-cataract ocular inflammation may cause visual impairment and pain.4 Although advanced surgical techniques have made cataract surgery less invasive and traumatic, pharmaceutical control of postoperative pain and inflammation remains an important element in the treatment process.5

Options for managing postoperative inflammation and pain in cataract patients include corticosteroids and NSAIDs.4 Corticosteroids are traditionally used for short-term control of inflammation.4 NSAIDs, which are used before and after cataract surgery to help reduce pain and inflammation, are cyclo-oxygenase (COX) inhibitors that work by suppressing production of prostaglandins.4

Choosing an Ophthalmic NSAID
Surgeons carefully select their post-treatment protocol, with an understanding that each ophthalmic NSAID has different molecular and formulation features.

A number of clinical factors drive ophthalmic NSAID prescription selection. The key molecular features of an ophthalmic NSAID include a high potency of COX inhibition (which contributes to control of inflammation and pain following cataract surgery) and good tolerability.6 The key formulation features include efficient penetration and rapid and sustained achievement of therapeutic drug levels (see box, “Clinical Factors That Drive Ophthalmic NSAID Prescription”). Ideally, the formulation should allow for early and prolonged control of ocular inflammation and pain and lessen the amount of time the drug remains on the ocular surface causing irritation.8

* Five pharmacists participated in the roundtable discussion. The pharmacists are paid consultants for Bausch + Lomb.
“When choosing an ophthalmic NSAID, special consideration must be given to the substantial number of patients with diabetes, a history of herpes virus, or chronic inflammatory diseases, such as rheumatoid arthritis and lupus,” Dr. Singh explained. “Many of these patients have corneal nerve insensitivities, which can interfere with tear film production and create a feedback loop that ultimately damages the ocular surface. This is one of the many reasons I prefer to limit exposure of a drug to the ocular surface, which impacts my choice of NSAID.”

Dr. Singh prefers to prescribe branded NSAID drops. In particular, for the treatment of post-surgical pain and inflammation in cataract patients, Dr. Singh prefers a branded NSAID formulation with convenient once-daily dosing, that does not require shaking, and has an established efficacy and safety profile. Dr. Singh prefers NSAIDs which are manufactured in an FDA-approved facility, rather than compounded formulations, for his cataract patients. Several of the roundtable participants noted that they work with surgeons who implant a high volume of premium intraocular lenses, and that those surgeons also tend to prefer branded drops.

“I try to minimize the dosing regimen and choose a drop that doesn’t require shaking,” Dr. Singh noted. “In my experience, many patients don’t shake their medication bottle even when instructed to do so. Failing to shake a bottle when necessary might negatively impact efficacy if the patient gets less than the intended amount of drug.”

SUBLITATIONS OF OPHTHALMIC NSAIDS

While many factors involved with the cataract surgery procedure are carefully controlled—from preparation of the ocular surface to the choice of intraocular lens to the surgical instruments used—postoperative treatment is out of the surgeon’s hands once the patient walks out of the office with a prescription. “We cannot completely control which drug is filled at the pharmacy, how the patient uses it, or even if the patient uses it,” Dr. Singh said. That’s why it’s so important for ophthalmic surgeons to reach out to their local pharmacists and make them an integral part of the cataract care team, according to Dr. Singh.

Several of the roundtable participants were surprised to learn that different ophthalmic NSAIDs may not be interchangeable, and some ophthalmic NSAIDs have no therapeutically generic equivalent. Many of the participants were also unaware of specific formulation differences among the ophthalmic NSAID class, such as the need for shaking or differences in dosing frequency.

Substitutions can create problems for patients because of differing instructions, according to Dr. Singh. “Let’s say an alternative formulation, which is dosed up to 4 times daily and requires shaking, is substituted for the prescribed drop, which has different dosing and shaking requirements. Patients may not realize that the instructions for the originally prescribed product, which came from the ophthalmologist’s office, do not apply to the substituted medication. As a result, in this example, these patients may use the medication only once daily and fail to shake the bottle, which can interfere with their post-surgical healing.” Nevertheless, substitutions are often made at the pharmacy for the...
prescribed ophthalmic NSAID. The roundtable participants identified a number of reasons for substitutions of selected NSAIDs. The two main reasons were lack of insurance coverage and cost. It is important to note that the participants in general mentioned a perceived lack of insurance coverage and cost concern within the class. It was for this reason they also acknowledged the importance of educating both the patient and pharmacist on the patient savings programs that may be available.

“We always try to dispense as written,” one roundtable participant said. “If the ophthalmologist prescribes a branded NSAID, we try to fill it. But the insurance company may say the drug isn’t covered.” Dr. Singh noted that patients are sometimes told a medication isn’t “covered” when in fact it isn’t “preferred.” A drug that isn’t “preferred” is still covered but may involve a higher copay. “Patients may not be familiar with these differences in terminology. That’s why eligible patients need to understand the savings programs that are offered and may be available to help address their cost concerns,” Dr. Singh said.

Sometimes an insurance provider’s Web portal will automatically recommend a different ophthalmic NSAID—either generic or another brand—if the prescribed drug isn’t covered or preferred. In those cases, a number of the participants stated that they try to call the prescribing ophthalmologist’s office for instructions. Dr. Singh noted that he and his colleagues prefer that the comanaging pharmacist call the practice instead of simply substituting the prescribed drug.

Socioeconomic class seems to play a role in who requests generics, the participants observed—but not always. For some patients, regardless of socioeconomics, the doctor’s prescription is “worth its weight in gold,” as one pharmacist put it. These patients are determined to obtain the exact drug prescribed, regardless of cost. According to the participants, patient education by their ophthalmologist regarding the choice of NSAID and the expected cost may impact whether patients obtain the ophthalmic NSAID prescribed by their surgeon. One pharmacist noted hearing on more than one occasion, “I know there may be a less expensive drop, but I want this one because it is what my doctor prescribed for me as a part of my treatment plan.”

In addition to lack of coverage and cost, the amount of time the pharmacist is given by the surgeon’s practice to process the prescription was identified as an indirect but very important reason for substitutions.

“We have developed a good relationship with several ophthalmic practices, and one of the reasons is that we try not to substitute initially,” one participant stated. “We try managed care first, then coupons, then prior authorizations—but we can only do that if we have enough time. Ideally, 2 to 3 weeks between the prescription and fulfillment is helpful in order to give us time to exhaust all possibilities before substitution.”

**BEST PRACTICES FOR NSAID FULFILLMENT**

All of the participants agreed that 2 to 3 weeks of lead-time helps them avoid substitutions and fulfill the ophthalmic NSAID prescribed by the surgeons.

Several of the participants stated that they appreciate when an ophthalmologist’s office sends the prescription for an ophthalmic NSAID to the pharmacy not only ahead of time but electronically. This allows the pharmacist to pull the patient’s insurance information and start working on the prescription before the patient even visits the store. For a number of the participating pharmacists, this is part of the customer service they want to provide.

“As both a pharmacist and a pharmacy owner, I feel I need to provide a high level of customer service,” one participant stated. “At my store, that means trying to preempt as many problems as possible by starting the prescription process early.”

Adequate lead-time also allows the pharmacist to ensure the prescribed product is on the shelf. “If I have 2 weeks of lead time, should I not have the product, I can order the product when I receive the prescription,” one participant stated. “In addition to identifying adequate lead-time as a best practice for ophthalmic NSAID fulfillment, the participants stated that building a relationship with the referring ophthalmologists in the area also helps to ensure that patients receive the medications they are prescribed.

“We have people coming from all over the city—from miles away—just to get their eye drop prescriptions filled. Why? Because we work closely with the ophthalmologists in the area. As a result, we understand not only how to process and use the coupons they provide patients, but we also know their post-surgical treatment protocol preferences and how best to communicate with the ophthalmologist’s office in order to take care of our customers,” one participant noted.

An in-person meeting between the ophthalmologist and the pharmacist can help cement a close working relationship. At least one of the participants stated that she has met with referring ophthalmologists to create a document, which is then signed by the doctor, listing the ophthalmologist’s first, second, and third choices for NSAIDs, steroids, and antibiotics. One of the benefits of this system is that there are fewer call-backs to the prescriber’s office. Dr. Singh added that he has a similar system in place with his local pharmacies.

Electronic communication—via text or email—is another way for ophthalmologists to build a relationship with comanaging pharmacists and communicate the reasons for their choice of NSAID. But, the participants added, it is important for the pharmacist to know the right person at the ophthalmologist’s office to contact with questions.

“We prefer to have a dedicated person, such as the surgical coordinator, to communicate with about prescriptions,” one participant stated.

Finally, all of the participants stressed the importance of education as a best practice for ophthalmic NSAID fulfillment: education of patients and of pharmacists.

First, patients need to be educated about why the ophthalmologist has chosen a particular medication, and how much it will cost, all of the participants stated.
**BEST PRACTICES FOR OPHTHALMIC NSAID FULFILLMENT**

- 2 weeks of lead-time from prescription to fulfillment
- Prescriptions sent electronically from the ophthalmologist’s office to the fulfilling pharmacy with “Dispense as Written” communicated on the script
- Close relationship between the ophthalmologist’s office and comanaging pharmacist, with in-person meetings if possible and identification of a main contact person at the ophthalmologist’s office for questions
- Clearly communicated surgeon prescription preferences for the post-surgical treatment protocol
- Patient education regarding rationale for selection of ophthalmic NSAID and expected price, whether it’s covered/preferred or not covered/preferred, and which programs are available so they may expect to pay no more than X with a coupon
- Pharmacist education regarding the clinical and formulation differences among ophthalmic NSAIDs, factors that may drive the ophthalmic surgeon’s treatment selection preference, and the full range of patient savings programs available to address any cost concerns

“The most successful relationships we have with ophthalmologists are the ones where the technicians really explain to the patient ahead of time why a particular medication was selected by the surgeon and how much it will probably cost if it’s covered or preferred, how much it will cost if it’s not covered or preferred, and what savings programs are available so they may expect to pay no more than X with a coupon,” one participant observed. “These patients, in my experience, are more likely to walk out of the pharmacy with the branded NSAID they were prescribed.”

Second, pharmacists should be better educated about why ophthalmologists choose particular medications, and about the available coupons, the participants stated.

“Before this meeting, I didn’t know a lot about the clinical and formulation differences between ophthalmic NSAIDs, or why ophthalmologists might choose one over the other,” one participating pharmacist stated. Another pharmacist acknowledged that he was unaware some savings programs were designed specifically to be used by eligible Medicare patients. All of the participants agreed that an ophthalmologist-provided list of ophthalmic NSAIDs, with their molecular and formulation characteristics, would be helpful in understanding the clinical rationale for selection and in explaining to patients why a particular medication was prescribed.

**CONCLUSION**

Some of the key takeaways from the roundtable identified by the participating pharmacists included a greater appreciation for the role of ophthalmic NSAIDs in cataract surgery and a deeper understanding of the molecular and formulation-related reasons that ophthalmologists prescribe particular ophthalmic NSAIDs.

Moreover, the group’s attitude toward substitution of ophthalmic NSAIDs had changed by the end of the discussion, with the participants stating they became much less likely to recommend a substitution for a prescribed ophthalmic NSAID.

Perhaps most importantly, the participants acknowledged the importance of developing a relationship with their referring ophthalmologists, a sentiment that was echoed by Dr. Singh. “I look at my comanaging pharmacists as an integral part of the cataract care team,” Dr. Singh emphasized. “The more we can bridge the gap between the prescriber and the pharmacist through education and communication, the better we can all serve our patients. I really believe that.”

**REFERENCES**


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