Confront Rising Drug Costs
Help patients and your bottom line

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JUDY HARRIS, Owner, Pharmacist, All-Care Pharmacy

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- Profit and Insurance Audit Protection
- Front End Inventory Management
- Advanced Bin Management
- Delivery and Remote Signature Management
- Compounding Toolset
SPECIAL REPORT > Pharmacists Step in for Dermatology Patients

Confront Rising Drug Costs
Help patients and your bottom line

INSIDE
OUTPATIENT CLINIC DRUG SPENDING SOARS
MEDICATION ADHERENCE TOOLS

New Drug Review
Betrixaban for Prophylaxis of Venous Thromboembolism
NEW for the treatment of Clostridium difficile–associated diarrhea (CDAD)¹

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.

- Otoxicity 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.

**Brief Summary**

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)

**INDICATIONS AND USAGE**

FIRVANQ™ 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.
- The effectiveness of VANQ™ 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, 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 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>Nausea</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Diarrhea</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Flatus</td>
<td>8</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Edema peripheral</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
<td>5</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Urinary tract infection</td>
<td>8</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Hypokalemia</td>
<td>13</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Back pain</td>
<td>6</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>7</td>
</tr>
</tbody>
</table>

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

**USE IN SPECIFIC POPULATIONS**

**Geriatrics**

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

**Pregnant women**

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

**Nursing mothers**

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

**OVERDOSE**

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

**PATIENT COUNSELING INFORMATION**

**Antibacterial Resistance:**

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

**Important Administration Instructions:**

Instruct the patient or caregiver to:

- Shake the reconstituted solutions of FIRVANQ™ well before each use and to use an oral dosing device that measures the appropriate volume of the oral solution in milliliters.
- Store the reconstituted solutions of FIRVANQ™ in the refrigerator when not in use.
- Discard reconstituted solutions of FIRVANQ™ after 14 days, or if it appears hazy or contains particulates.

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

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

Initial U.S. Approval: 1964 Manufactured for Cutis Pharma
841 Woburn St. Wilmington, MA 01887 USA
Rev. 2/2018
RISING DRUG COSTS

The rise in prescription drug prices is prompting pharmacists to become more proactive in helping patients save money.
The sharing of clinical data between pharmacists and physicians has often been, quite frankly, relatively paltry. While electronic health records (EHRs) vendors have shown little interest in investing in new development to provide clinical data to the pharmacist, the community pharmacist has been equally culpable due to the lack of consistent documentation in a usable structure with bedrock pharmacist interventions, such as drug therapy problems.

Highlighting this siloed approach to data isn’t breaking news to the industry, but an emphasis on improving quality over the past few years has fueled a renewed interest in breaking down the traditional barriers to exchanging data. The most exciting—and likely to succeed—answer to the interoperability conundrum in pharmacy has recently hit the market and is already receiving steady adoption: the Pharmacist eCare Plan.

The eCare Plan project, spearheaded by the Pharmacy HIT Collaborative, will result in an improved communication between pharmacists and physicians. Essentially, pharmacists will be able to update the eCare Plan with details regarding a patient’s current medication regimen and health concerns, including drug therapy problems, therapeutic goals, and medication support needs, in addition to the pharmacy’s interventions and the patient’s health outcomes. That information, through the eCare Plan, will be able to be received and consumed by any EHR, allowing the data to be used by the healthcare team in significant ways. Pharmacists who want to provide clinical services will want to use a vendor that harnesses this new technology.

Previous efforts to solve interoperability issues revolved primarily around the utilization of a single platform that both physicians and pharmacists could access. As you can imagine, the likelihood of engaging pharmacists and physicians on the same platform is minimal. The Pharmacist eCare Plan leverages the current clinical documentation system of the pharmacist to communicate clinical data. In order to transfer the data to an EHR, the document must be written in a common language and format. This language, known as HL7 has been used in the healthcare landscape for several years. Also, this language must also be adequately structured into a specific template. These pre-defined templates, called Clinical Document Architectures (CDAs), allow any EHR to read the document. The Pharmacist eCare Plan, while not yet approved by HL7 as an official CDA template, is already gaining steam throughout the country.

This new technology comes at an opportune time as healthcare is experiencing a rapid movement towards improving quality of care. Through the Pharmacist eCare Plan, pharmacists can provide interventions—such as diabetes education and chronic care management—and provide care coordination by sharing the information and formal plan with the rest of the healthcare team. As a result, the Pharmacist eCare Plan has already piqued the interest of payers looking to improve outcomes and reduce costs of high-risk chronic care patients.

Due to the new ability to share data with other healthcare providers, this technology has kickstarted a revolution in the community pharmacy industry, encouraging pharmacists across the country to engage their patients with clinical opportunities. This not only marks a significant—and blazingly fast—shift in the marketplace, but also serves as a launching pad for preparing community pharmacists for the next generation of pharmacy practice.

**FROM OUR BOARD**

David Pope, PharmD, CDE

**Prepare for a Revolution in Patient Engagement**

“This technology has kickstarted a revolution in the community pharmacy industry, encouraging pharmacists across the country to engage their patients with clinical opportunities.”

David Pope, PharmD, CDE, is chief of innovation and cofounder of Creative Pharmacist.
Prescription drug spending at outpatient clinics is expected to grow by 11% to 13% this year, according to new data.

“National Trends in Prescription Drug Expenditures and Projections for 2018,” published in the May 2018 AJHP online, also predicts that spending on prescription drugs at non-federal hospitals will remain unchanged or rise up to 2%.

Overall, national spending on prescription drugs this year is predicted to increase by 3% to 5% compared to 2017.

“Clinics’ spending increase has to do with the continued movement of care from inpatient to outpatient settings. It also has to do with the fact that most of the really expensive medications are used in clinics,” says lead author Glen T. Schumock, PharmD, professor and dean at the University of Illinois College of Pharmacy in Chicago.

Researchers also found that specialty medications could account for half of all U.S. drug expenditures by 2020.

Hospital pharmacists in Illinois are on high alert after an outbreak of severe bleeding and death among users of tainted synthetic cannabinoid products. State and federal public health officials say the outbreak appears to be linked to the presence of brodifacoum, a rodenticide, in the synthetic cannabinoid products, ASHP reported.

There have been 151 cases of severe bleeding, including three deaths, as of late April, the Illinois Department of Public Health reported.

Otherwise healthy patients present with spontaneous bleeding from the gums, vomiting of blood, blood in the stool, and nosebleeds.

Ahmed Mahmoud, PharmD, critical care and emergency pharmacist at Northwestern Memorial Hospital, tells ASHP that his chief concern is having an adequate supply of medications to achieve normal hemostasis.

Treatment largely consists of administration of phytonadione (vitamin K1) and, if needed, fresh frozen plasma. For life-threatening bleeding, administration of prothrombin complex concentrate may be necessary, he says.

Deaths, Injuries from Tainted Synthetic Cannabinoids Rise
Southeastern Grocers, the parent company of Winn-Dixie, BI-LO, and other supermarket chains, has partnered with Pathstone Health Services to offer personalized specialty pharmacy services to patients.

Specially-trained pharmacists offer personalized check-ins, reminders, and advice on medication side effects and potentially conflicting medications, Southeastern said. The service is designed to help patients with complicated medical conditions that are often chronic in nature such as cancer, hepatitis, multiple sclerosis, and Crohn's disease.

"We have listened to our customers and know there are medical conditions that require a specialty pharmacy in the communities that we serve," says Gayle Shields, vice president of pharmacy and operations for Southeastern Grocers.

Shields says that Southeastern can deliver customized specialty pharmacy care, including medications, clinical programs, financial assistance, and adherence monitoring all with convenient delivery options.

Increasing the number of vaccinations performed at pharmacies could significantly lower healthcare costs.

Studies show that pharmacies "tend to be more effective, lower-cost providers of vaccinations," said Pacific Research Institute in the report, "Promoting Access and Lowering Costs in Healthcare: The Case of Empowering Pharmacies to Increase Adult Vaccination Rates."

In a 2014 study, for example, researchers found that the average direct costs paid per adult vaccination were lower in pharmacies compared with physician offices by 16% to 26%, and by 11% to 20% lower in other medical settings.

"The evidence shows that pharmacists, when effectively empowered, play a valuable role in reducing the inadequate adult vaccination rate. Pharmacists provide vaccinations at lower costs, and with greater convenience, for many patients," the report states.

Pharmacists also provide valuable education services, such as advising on what other CDC-recommended immunizations that a patient should receive, according to the report.

Medical cannabis laws are associated with significant reductions in opioid prescribing in the Medicare Part D population, a new study says.

In the study, researchers found that, when a state instituted any medical cannabis law, prescriptions filled for all opioids decreased by 2.11 million daily doses per year from an average of 23.08 million daily doses per year in the Medicare Part D population.

Similarly, prescriptions for all opioids decreased by 3.742 million daily doses per year when medical cannabis dispensaries opened.

Hydrocodone use decreased 17.4%, when dispensary-based medical cannabis laws (MCLs) were put in place and by 9.4% with home-cultivation–only-based MCLs. Morphine use dropped 20.7%, when dispensary-based MCLs were allowed.

"Medical cannabis laws are associated with significant reductions in opioid prescribing in the Medicare Part D population. This finding was particularly strong in states that permit dispensaries, and for reductions in hydrocodone and morphine prescriptions," the authors write.

The study was published in the May 2018 issue of JAMA.

The combination of physical community pharmacies, telepharmacy, and technology can effectively treat patients — particularly those with chronic conditions, says a CVS Health executive.
of data-driven insights and the convenience of community-based retail healthcare can provide a highly personalized healthcare experience that supports the patient-centered medical home and can improve patient outcomes and lower costs.

Brennan discussed the potential for CVS Health to “create a new, unique chasis for population health management” by complementing the traditional use of telephonic case management with digitally-gathered information (such as a connected glucometer) and real medical intelligence, combined with in-person visits to conveniently located healthcare hubs based at MinuteClinic and CVS Pharmacy.

“We are looking to narrow the distance between patients in their everyday lives and the caregiving facility by leveraging digital data and making health care accessible in convenient community locations,” Brennan says.

Initial CVS Health pilot programs exploring retail-based population health management will focus on three target groups of patients: those with five common chronic diseases (diabetes, hypertension, hyperlipidemia, asthma, and depression); fragile patients who disproportionately drive a large percentage of total health care costs; and patients transitioning from a hospital setting, who require focused care to prevent readmissions and avoidable costs, according to Brennan.

More than two dozen Albertsons, Jewel-Osco, and Acme pharmacies are now offering a genetic test for patients with mental health issues. The test is the Genecept Assay, from Genomind, a company based in King of Prussia, PA. The assay identifies genetic markers that indicate which treatments are likely to work as intended, have no effect, or cause adverse effects for a specific patient.

Specially trained pharmacists at nearly 30 stores may decide to counsel a patient about the test if they see a pattern of the patient having unsuccessful experiences with medications prescribed for depression, anxiety, obsessive-compulsive disorder, or other mental illnesses.

“Up to half of all patients respond poorly to the first psychiatric medicine they try because everyone’s body is different, partially based upon their individual genetic makeup,” states Genomind in a statement.

After the counseling, if the patient agrees, the pharmacist contacts the treating clinician to suggest the Genecept Assay. “The pharmacist would be able to administer the test in a private area of the pharmacy; it involves collecting a small amount of saliva from the patient’s mouth with a cheek swab,” Genomind says.

The pharmacist would review the results of the genetic test with the patient after it’s returned from Genomind’s lab, which is certified through CMS’s Clinical Laboratory Improvement Amendments (CLIA) program. The clinician also receives the test results and could use it to help guide treatment decisions.

The Genecept Assay covers more than 20 drug classes, 122 FDA-approved medications, 18 clinically validated genes, and 97% of medications that are used to treat depression, anxiety, bipolar disorder, schizophrenia, attention-deficit disorder, and autism. It also offers comprehensive coverage of genes that can affect how well pain medications work.

Genecept has been shown in peer-reviewed published studies to improve patient outcomes and reduce overall medical costs, according to Genomind.

Christine Blank is a contributing editor.
The relentless rise in prescription drug prices is prompting pharmacists to become more proactive in helping patients save money. Community pharmacists have had a front row seat for the tsunami of prescription price hikes that has been building for decades. But recent changes have increased awareness and frustration among patients. “What has really caused it to bubble up above the surface are the high deductible plans, and also the changes in insurance plan designs [that] are shifting more of the cost burden to consumers,” says B. Douglas Hoey, RPh, MBA, CEO of Beth Longware Duff.
Coverstory

"CVS Health is giving expanded tools to patients, prescribers, and pharmacists so they can evaluate prescription drug coverage in real-time and identify lower-cost alternatives."

THOMAS MORIARTY

Could Policy Changes Combat High Drug Costs?

In May, HHS secretary Alex Azar outlined three broad areas that he plans to act on:

1. Restructuring how PBMs deal with drug manufacturers
2. Simplifying how Medicare pays for some expensive drugs
3. Making prices more transparent by requiring drug companies to include product prices in their television ads.

Meanwhile, many states are considering legislation to rein in costs. These laws focus on a number of issues including price transparency, PBMs, price gouging, importation, and volume purchasing.

PricewaterhouseCooper’s Health Research Institute’s 2018 annual report found that 21 out of 75 healthcare pricing bills considered in 2017 passed; only 15 such bills out of 72 passed in 2016.

Caswell, who ran unsuccessfully for the Kansas State Legislature in 2014, believes legislation is needed because government has a growing influence on the delivery of healthcare in the country. “There’s a saying that if you’re not at the table, you’re on the menu, and that’s really the case in healthcare,” he says. After a couple pharmacists were elected to the legislature in his state, Caswell says, “The dialogue of what pharmacies brought and the value that they have changed dramatically.”

Hoey believes the industry is at an inflection point, and that while there is pain there is also opportunity. He accepts legislation as a way to help return the marketplace to normalcy. In the meantime, he encourages pharmacists to keep tweaking their business model to stay competitive.

“What pharmacists are doing—looking at their cost of goods, looking at their contracts, looking at their opportunities to partner with other providers and local payers to choose a different option than their current PBM model—means there’s a lot of opportunities, especially for creative, ambitious pharmacy owners in the near future.”

Statistics released in mid-April offer some perspective. National health spending in the United States hit a seasonally adjusted annual rate of $3.6 trillion in February 2018, according to the nonprofit healthcare research and consulting organization Altarum. Expenditures for prescription drugs totaled $354 billion—approximately 10% of the healthcare total—and represented an annual growth rate of 4.2%.

Customer Relations Take a Hit

Naturally, pharmacies are bearing the brunt of patient frustrations with high costs. The J.D. Power 2017 U.S. Pharmacy Study reports “notable declines” in overall customer satisfaction that are driven by cost. On a 1,000-point scale, brick-and-mortar pharmacies fell 27 index points to 789 from 2016, while the in-store experience dropped 14 points to 851.

“Pharmacies have historically earned very high marks for customer satisfaction, so any significant year-over-year decline is cause for closer investigation,” says Rick Johnson, director of the Healthcare Practice at J.D. Power. “Consumer concerns about rising drug prices have likely affected perceptions of the cost for their retail prescriptions. The decrease in satisfaction with cost is the primary drag on overall customer satisfaction, creating a serious challenge for retailers.”

Brian Caswell, RPh, of Wolkar Drugs in Baxter Springs, KS, says price is a top concern for customers at his chain of stores in the southeast corner of the state. Many of them are struggling with escalating copays, lack of insurance, and tremendous increases in the cost of

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generics, specialty drugs, and biologics. When they voice frustrations over high costs, Caswell says having frank conversations helps them see him as a partner rather than the enemy. “Most patients understand, and they tell me that they know we’re not getting rich quick,” he explains. “I’ve even sat down and showed them our invoice prices and what the insurance pays. What’s funny is that the conversation goes from, ‘I can’t believe that the prices are this high!’ and, ‘How much are you making?’ to, ‘How can you survive?’”

In neighboring Oklahoma, Justin Wilson, PharmD, co-owns ValuMed Pharmacy in Midwest City and six other independent pharmacies. He says his long-term relationship with patients—some of whom began seeing his pharmacist father in the 1970s—makes it easier to talk dollars and cents with them. He uses various strategies to make their medications more affordable.

“We work with them and their physicians to get them on alternative medications to help reduce those costs. If they’re on Medicare, we work with them on getting manufacturer assistance program cards that help with the copay as well,” he says. “We’re pretty proactive with our patients, and I think that’s helped us to at least be a little more successful at dealing with those concerns.”

In addition to responding to patient frustration associated with rising drug costs, pharmacies are also dealing with the toll that it is taking on their businesses in the form of lower reimbursements.

**One National Chain Reacts**

The pressure to address soaring prescription drug prices has become a top priority for independent as well as chain pharmacies.

In April, CVS Health announced a comprehensive program called CVS Vermont Act 165

In the Spring of 2016, the Vermont General Assembly passed and the governor signed Act 165. The first-in-the-nation legislation attempted to stop what one legislator describes as “the unending instances of outrageous increases in prescription drug prices and the impact it has on the overall healthcare costs” for individual consumers and the State of Vermont. Two years later, he admits things didn’t exactly go according to plan.

“What we wanted to do was shine the light of shame on these drug companies,” says Rep. Bill Lippert (D), chairman of the state’s House Committee on Health Care. “I don’t think there’s anyone on our committee who feels satisfied that the law has achieved what we had hoped might be achieved.”

Act 165 directs the Green Mountain Care Board (GMCB) each year to identify up to 15 prescription drugs on which the State spends significant healthcare dollars, and for which the wholesale acquisition cost has increased by 50% or more over the past five years, or by 15% or more over the past 12 months. The Board gives the list to the Attorney General’s Office and posts it on the GMCB website. The Attorney General’s Office requires each drug manufacturer to justify the wholesale acquisition cost increase backed by supporting documentation. It then compiles an annual report to the General Assembly.

Lippert says the good news is all of the drug companies involved have provided some information. The not-so-good news? “They responded more as to what the pricing of drugs were rather than why these specific drugs went up during this specific period of time,” he says, calling their responses “general platitudes as to why drugs are so costly.”

This year the Vermont Senate is taking the lead to strengthen the existing law and/or propose other initiatives of a more significant nature, according to Lippert. On May 16, Gov. Phil Scott (R) signed legislation making the state the first to legalize importing prescription drugs from Canada. Other options under consideration include purchasing prescription drugs in bulk for distribution through the state’s pharmacy system and making pharmacist “gag clauses” illegal.

“It’s massively confusing for anyone to even sort out the complexities of all of this, much less to know which levers can you possibly move to make change,” admits Lippert, who remains optimistic nevertheless. “We hope to leave this session with some additional legislation that will move these issues forward for Vermont consumers and the State of Vermont’s cost of healthcare.”
Pharmacy Rx Savings Finder to help patients save money. CVS is rolling out the program to CVS Caremark PBM members and expects to gradually expand it this year.

Chief policy and external affairs officer Thomas Moriarty says the new program will help all parties to the transaction manage costs. “CVS Health is giving expanded tools to patients, prescribers, and pharmacists so they can evaluate prescription drug coverage in real-time and identify lower-cost alternatives,” he said when the program was announced. “We are committed to finding the right drug at the lowest possible cost for patients to ensure they are able to access and stay on the medications they need.”

Pharmacists can use the program to determine if the prescribed medication is on the patient’s formulary and is the lowest cost option. They can also learn if lower-cost options with equivalent efficacy of treatment are covered under the patient’s pharmacy benefit, or if the patient may save money by filling a 90-day prescription rather than a 30-day one. If a generic or lower-cost alternative is not available, the program provides other potential savings options for eligible or uninsured patients where allowed by applicable laws and regulation.

The new tool enhances existing savings opportunities that CVS Caremark offers, including preventive drug lists that make medications for many common chronic conditions available at no copay. The PBM also provides real-time member-specific drug costs and lower-cost alternatives to prescribers through their electronic health record system and to CVS Caremark members through the member portal and app. The company’s point of sale rebate also passes along negotiated rebates on branded drugs directly to patients when they fill their prescriptions.

Walgreen’s declined to comment specifically on the pricing issue.

**Business Implications**

In what might be considered a perfect storm, escalating prescription prices are also causing revenue problems for pharmacies, says Steven Giroux, RPh, owner of seven pharmacies in western New York. “When prices go up, payers—be they health plans or employers or PBMs on behalf of their clients—want a cut,” the NCPA past president explains. “And where do they turn to cut first? The easiest target is our reimbursement.”

Giroux recalls the 2016 controversy involving the 500% price hike for EpiPen that transpired between 2009 and 2016. Mylan’s CEO Heather

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**Breaking Down Prescription Drug Costs**

Figures released by NACDS in April dissect the cost of prescription drugs to show just how razor thin the margins are.

- About 80% of the average retail prescription price represents the pharmacy’s costs of purchasing the product from the manufacturer and the wholesaler.
- About 20% of the average retail prescription price represents the pharmacy’s gross margin on the prescription.
- More than 14% of that gross margin is consumed by pharmacy operational costs, including salaries, rent, utilities, the costs of maintaining and transferring inventory, and computer systems infrastructure.
- One to two percent of the pharmacy’s gross margin goes to pay state and federal taxes.
- After all expenses, the remaining net pharmacy profit on the average retail prescription price is about 2%.

NACDS recommends a number of policies to keep prescription drug prices to a minimum. They include increased use of generic drugs and biosimilars, reform of Medicare Part D DIR fees, improved medication adherence and MTM, and reformed FDA Risk Evaluation and Mitigation Strategy.

Source: NACDS

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**SOURCE:** Source: NACDS
Bresch testified before the House Oversight and Government Reform Committee in 2016 that Mylan made about $100 profit off each EpiPen two-pack, which had a list price of $608.

Giroux ran an analysis at the time and found that his gross profit from EpiPen transactions ranged from losing $5 to making up to $12. “Think about any industry in the world making a $12 gross margin on a $608 cost item,” he marvels. “That’s a miniscule gross margin, to say nothing of the fact that our cost to dispense with rent, heat, light, and salaries is obviously far greater than that.”

Generic drugs are another area of concern for pharmacists, says Hoey, but for a different reason. As a group, their cost is in decline, but he wonders how long that will last. “Generic Lipitor, generic Zocor, lisinopril, metformin—fantastic drugs, centerpieces of therapy for many disease states—are so inexpensive. We think that generic prices will skyrocket, which we’ve seen previously,” he says.

Zero reimbursements for many generics is common, says Giroux. He recently filled five prescriptions for one patient: omeprazole, lisinopril, metformin, amlodipine, and pravastatin. The total paid for the first four prescriptions was $6.83 in copays and nothing from insurance; the fifth prescription cost the patient nothing out of pocket and insurance paid $7.48. Great for the patient, not so much for his business.

“It’s very typical of what we do every day all day long—not a good long-term scenario,” says Giroux, who adds that 20% of the prescriptions his stores fill yield less than $5 total reimbursement. “Because of some generic price spikes in recent years, we were oftentimes underwater substantially.”

DIR fees add fuel to the fire of declining reimbursements. A recent NCPA survey reveals that an overwhelming majority of independent community pharmacists say retroactive DIR fees undermine patients’ access to prescriptions and hinder their own ability to manage their businesses. Eighty-four percent of respondents say they never know what their final reimbursement will be at the point of sale; 77% report that it could take up to a year before they had that information.

“When you see dwindling reimbursements and unnecessary retroactive fees and all sorts of things that are putting pressure on the business side, it’s hard to keep the doors open and continue to provide services to our patients,” Wilson says.

**Revenue Boosting Options**

Wilson is exploring alternative revenue streams—including chronic care management—and efficiency improvements.

“It’s tougher than ever on the financial side. We’re really trying to focus on finding ways to continue to provide a high level of care to our patients,” says Wilson.

He adds that when you see dwindling reimbursements and unnecessary retroactive fees and all sorts of things that are putting pressure on the business side, it’s hard to keep the doors open and continue to provide those services to patients. “We’re working hard, though, and trying to figure out ways to do alternate revenue streams or improve efficiencies and make this model work so that we can continue that one-on-one relationship and ultimately hopefully improve patient care outcomes.”

**Alternative Revenue Streams**

For some pharmacies, it’s getting harder and harder to make a living just filling prescriptions, and as a result, Wilson says that he is exploring other opportunities. “How can we bring in services that improve the health of our patients and generate revenue outside of being tied to a drug product? Chronic care management is something we’re exploring, collaborating with physicians to help improve patient care outcomes and be able to get paid under Medicare Part B versus Part D.”

Wilson says that he’s always tried to make business decisions based on the needs of patients. “I still believe that, but I think it’s getting harder and harder. We’re at a critical point in the reimbursement model that we have right now.”

Caswell is expanding over-the-counter medications and products in his stores. He’s also exploring ways to open new revenue streams, including offering immunizations, diabetes and cardiovascular education, smoking cessation, and nutrition classes. But in order to do that, he says he’d have to hire another pharmacist to either provide the services or cover for him while he does it. “I’ve got to be able to balance another salary with the potential revenue for offering those classes.”

Beth Longware Duff is a contributing editor.
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No one gets through life without the occasional rash, sunburn, or patch of itchy, dry skin. Less fortunate individuals suffer with chronic severe skin conditions, such as psoriasis, eczema, acne, or rosacea. Effective prescription treatments can give greater relief and in some cases, result in complete remission, but these drugs may carry large price tags. Specialty pharmacies are helping patients with dermatology issues get their medications without breaking the bank.

Many patients with severe skin disorders have gone from general practitioners to dermatologists or even to a series of dermatologists because their conditions are more extensive or are recalcitrant. Take psoriasis for example. These patients may have already been treated with the usual first-line treatments and either did not respond or did not respond well enough.

“They’ve been through other dermatologists, now they’re coming to a larger academic medical center because they have more going on. So a lot of times they need the biologic treatments,” says Audrey Rutledge, PharmD, BCACP, a MARC-prior authorizations pharmacist at the University of Colorado Hospital in Aurora. MARC stands for Medication Access and Renewal Center, a program that helps patients obtain access to high-priced specialty medications through third-party payers. “Our department specializes in getting access to high-cost medication.”

The current healthcare climate has facilitated the emergence of these specialty pharmacies, says Adam Friedman, MD, FAAD, associate professor of dermatology at George Washington School of Medicine and Health Sciences in Washington, DC. Getting prior approval for those drugs, or getting a third-party payer to reconsider a denial, takes times and effort. With a specialty pharmacy, “you have people who are more knowledgeable about navigating through the various impediments that insurance has put into place to get these types of drugs covered.”

Friedman compares the process to a dance. “It’s going back and forth with paperwork, explanations, written documentation. If you know the dance, then you know how to win the competition, so to speak.” Specialty pharmacists know the system and it takes a lot of the burden off the physician, he explains. “It’s a wonderful symbiosis. It really makes our lives so much easier. And it fast tracks the patients to getting their medications.”

Standing Up for Patients
Many autoimmune skin conditions are effectively treated with pricy biologic medication. (See Table 1.) But it isn’t just about biologics, Friedman says. Nonbiologic drugs, “whether it be for common diseases like rosacea, acne, eczema, psoriasis, there are a lot of new formulations which insurances will reject,” he says. Insurance companies frequently want prescribers to choose older generic formulations that may not work as well for a given patient.

Rutledge and her MARC colleagues have seen insurance companies deny newer formulations of topical steroids for patients who don’t respond to other versions, such as first-line topical steroids or topical calcineurin inhibitors. “Based on wherever a skin condition is, the absorption rates can change,” she says, which can interfere with the effectiveness of older formulations. A foam formulation for a drug like clobetasol may not be the version preferred on the formulary and getting that product for a patient can take the intercession of a specialty pharmacist, she notes. Clobetasol foam can cost between $110 and $300 per 50-g can.
Allison Vidimos, MD, RPh, praises the help that specialty pharmacists have offered her patients who have metastatic basal cell carcinoma, for whom she prescribes vismodegib (Erivedge, Genentech). Vidimos, who worked as a pharmacist while she was in medical school, is chair of dermatology at the Cleveland Clinic. Vismodegib can cost $8,000 to $9,000 per month, she says. “It is a specialty medication that our specialty pharmacy has done an incredible job in getting it for the patients in a timely fashion, and getting it covered either completely or almost completely.”

In some cases, a third-party payer may not consider the condition an urgent matter or view it as merely a cosmetic condition. Rutledge says. She notes that her department has helped some patients with alopecia obtain tofacitinib citrate (Xeljanz, Pfizer), despite it being off-label for that condition.

However, more insurers are starting to understand the quality-of-life problems created by chronic skin conditions. “Even something like acne can be extraordinarily debilitating and affect someone’s professional and social choices,” Friedman says. “We are moving in the right direction, but there is a big focus on proving that skin disease has a tremendous burden on the general population.”

Once the MARC team is involved, very few patients decide against using a medication because of its cost, says Rutledge. She describes what she does as “almost like a form of case management where we’re doing so much personal outreach to the patient.” With that outreach, they can also determine if the patient is adhering to their medications or needs to be switched to another drug, she says.

Role of Community Pharmacists
Community pharmacists may be the first healthcare provider patients with a rash might go to for a recommendation regarding an OTC remedy. But they should also be prepared for patients who may present with more serious conditions. Rutledge used to work in community pharmacy and often had patients ask about skin problems. “They would do it frequently enough that I would look up information . . . at least for my own benefit,” she says. “Most of the time, you end up referring them to their provider because it’s something that you know needs to be assessed.” She has used Uptodate.com, an online subscription clinical decision resource, since it has a lot of photos of various skin conditions. “But I think following any education opportunities from ACPE-accredited bodies, trying to get some CE in there, is a good idea.”

Rutledge and Vidimos stressed that pharmacists who are asked to recommend OTC products for a skin condition should tell patients to see a physician if the problem does not go away in one or two weeks. “You’re really not going to hurt someone with a lot of the over-the-counter stuff,” Friedman says, “because most of these types of things that someone would probably show to a pharmacist should improve with the right treatment in about a week or two.”

Friedman also suggests that pharmacists advise someone with a rash to take a photo of it before they start using any OTC product. This creates a record of what the rash looked like before any treatment, and it can be shown to a physician later on, if needed.

Pharmacists can also recommend that patients with a skin issue go to an urgent care center, Vidimos says. “A lot of times it would merit sending them to a facility like that where they can be looked at quickly and diagnosed and sent on their way.”

Valerie DeBenedette is managing editor of Drug Topics.
Blue Cross Blue Shield of Michigan (BCBSM) is teaming up with Michigan Medicine, the large healthcare system operated by the University of Michigan, to embed ambulatory care clinical pharmacists in primary care settings across the state.

Pharmacists participating in the initiative, the Michigan Pharmacists Transforming Care and Quality (MPTCQ) program, operate under collaborative practice agreements with physician organizations. They can make medication changes and provide disease state management in the areas of diabetes, hypertension, and hyperlipidemia. The pharmacists also provide comprehensive medication review services and work in tandem with primary care physicians to address patient needs. The program is unique because of its wide-scale adoption across the state and its support from the state’s largest commercial payer.

The program also includes a structured and standardized training and mentoring program targeted at pharmacists as well as physician organization leadership to ensure the success of embedding pharmacists into clinical practice.

“BCBSM helped support us to build a coordinating center at University of Michigan to help provide training, support, and tool kits, and really help our other organizations around the state to implement a pharmacist into the care team and primary care,” says Hae Mi Choe, PharmD, associate dean for pharmacy innovation and partnerships at the University of Michigan College of Pharmacy in Ann Arbor. Choe is in charge of the program.

To date, 30 pharmacists are embedded in 52 practice sites across the state. Pharmacists work directly within the primary care clinic. One pharmacist may spend a portion of a day or several days within a clinic each week, depending on the clinic’s need. The program, which began in 2015, has helped 7,685 unique patients so far, for a total of 23,701 patient encounters. BCBSM pays pharmacists for the visits they conduct with patients and helps physician organizations offset a portion of the cost of employing a pharmacist on site during the first two years they participate in the program.

Patients are either referred to the pharmacists or pharmacists can recruit patients themselves by identifying those who are having difficulty meeting their targeted therapy goals.

“They all have their own schedule in the clinic so that patients can be referred and [pharmacists can] see patients independently and be able to assess their disease control as well as reviewing their medications,” says Choe.

**Improving Patient Care**

Choe and her colleagues are tracking a variety of outcome measures, including medication adherence statistics, patient data on controlling blood pressure, and improving patients’ A1c numbers, in an effort to demonstrate the value pharmacists bring to primary care settings.

They plan to report on these outcomes in upcoming studies; however, Choe says she’s already seen the tremendous value pharmacists can provide. “While physicians might be more focused on diagnosis and treatment, our specialty is really on the management or treatment of chronic conditions. That’s where I think we could offer a different perspective and a different skill set that physicians may not have, given the complexity of the medications,” she says.

Having dedicated pharmacists who are charged with optimizing treatment regimens, improving patient engagement, and providing enhanced education, also lessens physicians’ workloads and improves the quality of care, Choe says.
How to Deal with Pharmacy Robbery

Have a plan in place for what to do—and what not to do.

With the increase in pharmacy robberies and burglaries in recent years, every pharmacist wonders how they will handle a robbery situation when they are faced with it.

In one recent case, Don Zimmerman, 75, pharmacist and co-owner of Purdy Cost Less Pharmacy in Gig Harbor, WA, tackled a masked robber. The 21-year-old male was attempting to steal a bottle of cough syrup containing codeine. “He’s trying to gouge my eyes, but I don’t feel it because I got a case of adrenaline,” Zimmerman tells K5 News.

“Pretty soon I said, ‘is there any men out in the store?’ Well, three guys come back and believe it or not they are almost my age. So, we got the geriatric group going up against this young guy.”

When law enforcement arrived, they found the suspect—who had a plastic toy revolver—pinned to the floor with two men holding his arms behind his back.

Fortunately, in this case, the pharmacist and pharmacy staff were not harmed—except for a few “nicks,” according to Zimmerman.

However, law enforcement experts tell pharmacy staff not to take matters into their own hands when faced with an armed robber.

“You need to set the price higher for your personal safety rather than any object,” Richard Logan, PharmD, owner of L&S Pharmacy in Charleston, MO, and a recently-retired sheriff’s deputy, tells Drug Topics. “The primary concern is getting everyone out of the pharmacy with no harm to anyone.”

The best thing pharmacists can do to prepare for pharmacy robberies is to have a plan in place, “and you need to convey that plan to all the pharmacy staff,” Logan says.

“These decisions have to be made in real time; that’s why you have a plan in place,” Logan adds.

Instead of tackling or fighting the suspect, pharmacists and pharmacy staff may want to press a panic button that notifies police. They should also get a good description of the robber to share with law enforcement, he says.

Logan also advises pharmacists not to arm themselves, unless they are “trained, practiced, and able to look someone in the eye and take their life. When anyone pulls out a weapon, the conversation is over. You are in a life and death situation at that point.”

Christine Blank is a contributing editor.
Some patients with life-threatening diseases will now be able to receive experimental treatments without receiving approval for their use from the FDA first. On May 30, President Trump signed the Right-to-Try Act into law.

Under the law, patients can access experimental treatments if they are unable to participate in any clinical trial involving an investigational drug and if they have exhausted all other approved treatment options. The bill requires that any unapproved drug must have an active application and not be subject to clinical hold. In addition, the government may not use a clinical outcome associated with use under the legislation to delay or adversely affect a product's review or approval, unless it is critical to determining its safety or the sponsor requests use of the outcome.

Proponents and critics of the law have a lot to say about its potential effects.

**What Proponents Say**
Starlee Coleman, senior policy advisor, at the Goldwater Institute, says the FDA is the ultimate arbiter of which drugs should be made available. Still, she believes that the current FDA approval requirement under the Expanded Access Program takes too long.

“We don’t think Americans should have to apply to the government to save their lives,” she says. “The government shouldn’t be able to say ‘no’ if a manufacturer and doctor approve. Right-to-try provides access to potentially life-saving treatment for patients without other options who cannot get into a trial.”

Coleman says drugs available through Right to Try have passed phase 1 trials and continue to be tested, making them safe enough for terminal patients while offering possible benefits. “Right to Try could be particularly beneficial if a trial ends with positive results, but a drug has not yet been approved,” she says.

**What Critics Say**
The most virulent opponents of federal right-to-try legislation say that it is not significantly different from Expanded Use but is part of an effort to reduce the regulatory scope of the FDA and federal government in general, says Harold Bishop, senior legal analyst, Health Law Group, Wolters Kluwer, a global information company.

Other criticisms, according to Bishop include:
- Lack of FDA involvement could reduce safety because information about a product’s use would not be available.
- Right-to-try could drive patients away from clinical trials if they could obtain investigational drugs without participation.

Arthur Caplan, PhD, director, Division of Medical Ethics, New York University’s Langone Medical Center, says proponents of right-to-try legislation seem to overlook the fact that the FDA is not, in general, a significant barrier to access to products. Most requests for expanded access are granted.

**The Manufacturer’s Role**
Under both Expanded Access and Right-to-Try laws, manufacturers may choose whether to make an investigational drug available. Drug manufacturers may be hesitant to provide preapproval access because of a limited supply of the drug. Also, if a patient suffers adverse effects when they try it, that might deter other patients from participating in clinical trials or from purchasing the product after FDA approval.

The Pharmaceutical Researchers and Manufacturers of America has not taken a formal position on right-to-try as yet. Still it has created criteria for determining when to grant access to an experimental treatment.

Mari Edlin is a contributing editor.
Preparing for pharmacy policy changes can help you stay ahead of the competition. Here, pharmacy experts highlight three areas to watch.

1 **340B**

   Through the 340B program, pharmaceutical companies participating in Medicaid agree to provide outpatient drugs to eligible entities at reduced prices. Hospitals and clinics that participate must apply for eligibility and meet specific requirements, says John M. Lonie, RPh, EdD, associate professor of social and administrative sciences at Long Island University College of Pharmacy (LIU) in Brooklyn, NY. “The program enables covered entities to stretch federal resources and provide more comprehensive services.”

   The 340B program has grown because of changes that increased opportunities for purchasing discounted drugs and because eligible entities became more aware of it, says Emily Cook, MSPH, JD, partner, McDermott Will & Emery, an international law firm.

   The 340B program has grown because of changes that increased opportunities for purchasing discounted drugs and because eligible entities became more aware of it, says Emily Cook, MSPH, JD, partner, McDermott Will & Emery, an international law firm.

   The program’s growth has led to scrutiny from many healthcare stakeholders, who are concerned it is not governed by clear rules, making it difficult to hold participating providers and drug makers accountable for compliance with requirements, Cook says. For example, drugs purchased by providers through the 340B program cannot also be eligible for Medicaid discounts, and drug makers must accurately calculate 340B prices.

   Chris Hudson, managing director, Dacarba LLC, a professional services firm, points to questions about eligibility rules and if they are restrictive enough, as well as the lack of transparency around how savings are used.

   Five bills concerning the 340B space have been introduced and additional bills are coming, Cook says. .

2 **Provider Status**

   Pharmacists and the patient care services they provide are not included in the Social Security Act, which determines eligibility for programs such as Medicare Part B. The omission limits Medicare beneficiary access to pharmacist services in an outpatient setting. If pharmacists were designated as providers under Medicare Part B, private health plans could not use this as an excuse to exclude pharmacists as providers, says Fernando Gonzalez, RPh, MS, assistant professor of pharmaceutical sciences at LIU. “Pharmacists are now on the verge of obtaining provider status as a result of many states pushing for this status,” he says. “Once the federal government grants provider status, states will follow suit.”

   Provider status will allow pharmacists to bill for services, and receive payment from Medicare, Medicaid, and other private payers, Gonzalez says. In some states, pharmacists could be allowed to provide services to Medicare patients as nurse practitioners and physician assistants do. These services might include monitoring drug levels, side effects, adverse reactions, and compliance; and ordering diagnostic tests .

3 **Orphan Drug Designations**

   The Orphan Drug Act provides benefits and incentives to drug companies that address rare diseases that affect fewer than 200,000 people. If a condition affects more people, the company must prove it cannot reasonably recoup costs associated with the drug’s research and development.

   Orphan designation gives a drug seven years of market exclusivity, sizable tax credits, and other benefits, says Edward Buthusiem, managing director, Berkeley Research Group, a strategic advisory and consulting firm. Many drugs receiving orphan designation are older versions of drugs that may have been sold for many years and have no patent protection, Buthusiem says.

   Orphan drugs tend to cost more than nonorphan drugs, Buthusiem says. However, the higher price extends to the nonorphan indications of these drugs. This lack of price differentiation between orphan and nonorphan indications has drawn the ire of Congress, .

   The Closing Loopholes for Orphan Drugs Act is one bill to watch. Currently, orphan drugs are excluded from the 340B program to avoid invalidating company incentives to develop such products. Drug makers are not required under the 340B program to discount orphan drugs. If passed, it would limit the 340B drug pricing program’s orphan drug exclusion to apply only when a drug is used for the rare disease it was developed to treat.

   “That would allow orphan drugs, which are often very expensive, to be discounted under the federal program when they are used for nonorphan diseases or conditions,” Buthusiem says.
A new study reveals that drug indications data from a drug knowledge base can differentiate between many look-alike-sound-alike (LASA) drugs that are easily confused. The finding may add impetus to the push to add indications to prescriptions.

“It can be easy to confuse two LASA drugs. Having the indication for a drug can help pharmacists recognize potential LASA drug errors, particularly if the indications for two LASA drugs are very different,” says Christine Cheng, PharmD, lead author of the study.

Cheng, a clinical pharmacist in the Disease Decision Support Group at First Databank Inc., says the study sought to determine to what extent LASA drugs on the Institute for Safe Medication Practices’ (ISMP’s) list of easily confused drug names could be differentiated by high-level/general indications from a commercial knowledge base. A knowledge base is an advanced type of database.

Results of the study were published in the May 2018 issue of the Journal of the American Medical Informatics Association.

Cheng says that the study used ISMP’s list of easily confused drug names as its list of LASA drugs. The source for indications was a commercial knowledge base (First Databank MedKnowledge Indications Module) that includes both FDA-approved and off-label indications for drugs.

The study excluded certain drugs from the ISMP list. For example: drugs no longer marketed or not marketed in the United States, medical supplies, medical devices, and dietary supplements. It evaluated 278 pairs of drugs with LASA names involving 452 unique drugs.

There were 165 (59%) LASA pairs with no overlap in high-level indications, 58 (21%) LASA drug pairs with partial overlap, and 55 (20%) LASA drug pairs with complete overlap.

“This means that the majority of LASA drug pairs on the ISMP list could be differentiated with even high-level general indications. Had we used more granular indications, we likely would have been able to differentiate even more LASA pairs.

Patient Safety

Cheng said if pharmacists and physicians know what the purpose of the drug, it’s easier to see if the dosing is right, if it’s the right regimen, and if the patient carries the correct diagnosis. “It’s empowering them to know they’re taking each of their medications and to ask questions.”

Anthony Vecchione is the executive editor of Drug Topics.
Gene Therapy Advances: What You Should Know

Although only three gene therapies have been approved in the United States, these treatments are leaving their imprint on the healthcare system.

Three gene therapies have been approved in the United States and they are already having an impact on the healthcare system.

They are Novartis’ Kymriah (tisagenlecleucel), a chimeric antigen receptor (CAR) T-cell therapy for certain cases of acute lymphoblastic leukemia; Kite’s Yescarta (axicabtagene ciloleucel), a CAR T-cell therapy for non-Hodgkin lymphoma; and Spark Therapeutics’ Luxturna (voretigene neparvovec-rxyl) for retinal dystrophy. Luxturna is the first gene therapy to be administered directly into cells, delivering a normal copy of the RPE65 gene into the retina.

Price tags for these therapies are unprecedented but not unexpected. Luxturna is $850,000 per course of treatment, Kymriah for $475,000 per course, and Yescarta for $373,000 per course.

How It All Works
Gene therapy restores an abnormal or mutated gene by introducing genetic material into cells via a carrier called a vector. Vectors are usually retroviruses or adenoviruses.

Genome editing allows DNA to be inserted, deleted, modified, or replaced in a human cell to correct defective DNA. Editing can eliminate problems in DNA and remove deadly inherited diseases using CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats).

“Gene editing has tremendous promise; it can fight back against cancer by making cells resistant,” says Ben Solomon, managing director, GeneDx, a genetic testing company.

As with any new medical technology, promoting efficacy, safety, and limiting side effects are prime objectives. Terence Flotte, MD, provost dean and professor at the University of Massachusetts Medical School, says gene therapy treatments could face problems if vectors cannot deliver enough of a correct virus into a sufficient number of cells to make a difference.

Christos Kyratsous, senior director, infectious disease and viral vector technologies at Regeneron is concerned about how patients’ immune system will respond to gene therapy.

“Vectors and/or viruses are foreign to our body; our immune system might start to fight against them and generate a response against it. We are trying to understand this process and exploring ways to avoid it from happening.”

Sam Falsetti, PhD, head of medical strategy at Cambridge BioMarketing, a communications company, says one of the biggest challenges creating a barrier to gene therapy is the lack of treatment centers across the country.

Payment models
One of the most ambivalent issues surrounding genetic therapy and editing is insurance coverage. Falsetti is unsure whether committing to a million-dollar price tag for gene therapy holds more value than spending money for traditional therapy.

Spark has three payer programs for Luxturna. The first arrangement provides rebates to an insurer if patients fail to meet a specified threshold of short-term efficacy and long-term durability of the treatment. Spark’s rebates will not exceed those of Medicaid.

“We are looking at innovative efficiencies by targeting the right population,” says Michael Sherman, MD, chief medical officer at Spark. “Luxturna could be life-changing although expensive. It is difficult to pay such a high price if a drug fails.”

It’s critical to look at outcomes compared to costs, he says.

Sherman says Harvard Pilgrim will cover Luxturna despite the price—especially when downstream costs of social services, family support, and the small number of patients are taken into consideration.

Bill Martin, vice president and general manager at Accredo, says the tab for Luxturna should not be too high for any one insurer, as there are only about 1,000 people with retinal dystrophy in the United States.

Novartis also has developed a value-based arrangement with CMS in which the manufacturer will only accept full payment after patients respond to Kymriah by the end of the first month of treatment.

Mari Edlin is a contributing editor.
Why You Should Consider Board-Certification in Oncology

Cancer treatment developments present new opportunities for pharmacists.

The increasing number of drugs and complexity of drug therapy in the treatment and prevention of cancer requires advanced and specialized knowledge and experience. Board-certified oncology pharmacists (BCOPs) are stepping in to meet this need.

Oncology pharmacists represent a broad range of expertise and work in a variety of settings. Most commonly, they provide direct patient care using an evidence-based patient-centered medication therapy management approach. However, they may also be involved in nondirect patient care, such as practice management, investigational drugs or clinical trials, pharmaceutical industry, regulatory agencies, and health plan sponsors/pharmacy benefit managers. In many cases, an advanced level of certification can allow for a higher salary, promotions, and new practice opportunities.

Certification allows me to practice at an advanced level of pharmacy practice in a complicated disease state, and work in multiple practice settings. Currently, I work in a team-based practice alongside a medical oncologist. Together we review patient histories and develop cancer treatment plans throughout these patients’ disease. My expertise in understanding the complex therapies is important to effectively monitor for and prevent and manage cancer- and drug-related adverse events. I’m recognized by my institution and profession as someone who is well-qualified to be a provider on the healthcare team.

The credentialing process, through BPS, ensures that pharmacists have the advanced knowledge and expertise to optimize cancer patient outcomes through:

1. Recommending, designing, implementing, monitoring, and modifying pharmacotherapeutic plans
2. Reducing medication errors
3. Recognizing and responding to adverse events that may arise during treatment
4. Providing education and counseling

Several pathways exist to board certification. Most commonly, pharmacists complete an advanced pharmacy practice residency in oncology or participate in on the job training. However, the only formal method to determine if pharmacists are qualified to contribute at advanced practice levels is the Board of Pharmacy Specialties (BPS) oncology pharmacy board examination.

To take the oncology board-certification exam, pharmacists must complete a:

- Postgraduate year 1 (PGY1) general residency and a PGY2 oncology residency program;
- PGY1 program and two additional recent years of oncology pharmacy experience after licensure; or
- Four years of recent oncology pharmacy practice experience.

Recertification must be done every seven years and can be accomplished through re-examination or completion of 100 hours of continuing education specifically designated as BCOP appropriate.

Certification in oncology allows the pharmacist to demonstrate to the healthcare team, employers, and patients/caregivers that he/she is uniquely trained and educated to meet the specialized needs of oncology patients. The oncology pharmacy board exam ensures that the pharmacist has a thorough knowledge of pathophysiology and molecular biology of cancer; therapeutics, patient management and education; clinical trials and research; practice management; and public health. With this knowledge, they have the unique expertise to be able to manage cancer- and treatment-related problems that are not encountered in other disease states.

Lisa M. Holle, PharmD, BCOP, is an associate professor of clinical pharmacy, UConn School of Pharmacy, Storrs, CT.

REFERENCES
Conscience Clauses: Refusal to Fill Prescriptions

If a pharmacist is convinced that filling a prescription is not in the best interest of the patient, due to an allergy or contraindication, the pharmacist may be under a professional duty to refuse to fill, at least until he or she contacts the prescriber to resolve the question. Similarly, if the pharmacist believes the prescription is illegal, the purported prescription is not legal and not a valid order. It may not be filled, at least until questions are resolved.

A more difficult question is raised if a pharmacist refuses to fill based upon his or her religious beliefs. In July 2002, a University of Wisconsin student requested a refill on her birth control prescription at her local pharmacy. The pharmacist on duty, Neil Noesen, RPh, refused to fill it citing his religious beliefs. He also would not transfer the prescription or tell her where she could get it filled. The student filed a complaint with the Wisconsin Board of Pharmacy. The board’s administrative law judge restricted Noesen’s license, finding that a pharmacist with a conscientious objection to dispensing a prescription must ensure there is an alternative mechanism for the patient to receive the medication, including informing the patient of their options to obtain their prescription.

Noesen appealed the decision. The Court on appeal ruled, “Noesen had a right to refuse to provide birth control pills but not to refuse to transfer a valid prescription to another pharmacy.”

In 2012, the Washington State Pharmacy Quality Assurance Commission passed a regulation stating that all pharmacies “must stock and dispense emergency contraceptive drugs” regardless of religious or moral reasons. A federal court judge originally ruled the regulation violated the religious freedom of pharmacy owners, however a unanimous federal appeals court panel overruled this in 2015. The Court of Appeals decision was appealed to the United States Supreme Court. The Supreme Court refused to hear the case, leaving the appeals panel’s ruling as the final decision on the case.

Reports of pharmacies refusing to fill prescription for birth control or provide emergency contraceptives have arisen in 26 states, according to the National Women’s Law Center. Regulations allowing pharmacists to refuse to fill are in effect in at least seven states, while a similar number require pharmacists to fill the prescriptions.

The American Civil Liberties Union (ACLU) has stated it hopes to increase enforcement of laws that protect workers from being forced to violate their consciences, according to the article.

Pharmacists must be familiar with their state regulations and new federal guidelines.

Reference:
What Healthcare Executives Think About Pharmacy Challenges

Pharmacists, whether they work in or out of health-system pharmacies, often must deal with decisions made by healthcare leaders. To learn more about what’s on their minds when it comes to pharmacy, here are some statistics from a survey done by Managed Healthcare Executive, a sister publication to Drug Topics. The survey was conducted during the first quarter of 2018. The survey received more than 100 responses from executives at medical practices, hospitals, large healthcare systems, benefit management organizations, health plans, long-term care organizations, group purchasing organizations, consulting firms, and more.

What is the most effective way to reduce pharmaceutical costs (specialty and non-specialty)?

- Increased collaboration to identify the most effective and cost-effective treatments (51%)
- More aggressive and expanded utilization management strategies (e.g., prior auth, step therapy, and limited initial refills) (17%)
- Adoption of more stringent, evidence-based clinical pathways (15%)
- More narrow and/or exclusionary formularies (4%)
- Other* (13%)

*Other responses included: More use of generics, government subsidies for specific more expensive drugs, more government interference, pharmacy case management for specialty drugs

Will biosimilars reduce specialty drug costs?

- Yes, starting in 2018: 25%
- Yes, starting in 2019: 16%
- Yes, starting in 2020: 12%
- Yes, post-2020: 15%

“When it comes to working toward a more collaborative system, it’s all about the alignment of incentives. We need to demonstrate efficacy and then give the physicians a reason to care about prescribing the most cost-effective treatment.”

—Managed Healthcare Executive editorial advisor Doug Chaet, chief managed care officer, Sentara Healthcare, and chairman, American Association of Integrated Healthcare Delivery Systems

“As noted in the survey responses, the promise of biosimilars is always one or two years away. Thus far, specialty drugs in the same class (e.g., TNF inhibitors) have, if anything, increased total spend. Saying that, at some point biosimilars should have the same impact as generics and reduce total drug spend.”

—Editorial advisor David Schmidt, president of the TPG International Health Academy and a healthcare consultant
Industry Topics

“In the long term, pharmaceutical companies need to tie their drug pricing to outcomes. Since health plans have medical and pharmacy claims data, they can calculate ‘total cost of care’ for patients with certain diseases that are treated by specialty pharmaceuticals and can therefore measure the benefit of value of these medications on total healthcare spend. This means they have the ability to do outcomes based contracting and make pharmaceutical companies price their drugs accordingly.”

— Editorial advisor Perry Cohen, PharmD, CEO of The Pharmacy Group and the TPG family of companies

**Q.** What is the biggest opportunity to reduce specialty pharmaceutical costs?

- Performance-based (outcomes-based) pricing: 39%
- More aggressive and expansive utilization management strategies: 23%
- Exclusive specialty pharmacy contracting: 11%
- Increased government regulation: 10%
- Formulary exclusions: 5%
- Other*: 12%

*Other responses included: Increase formulary addition of biosimilars, more competition on the product and supply chain side

**Q.** What is the best coverage strategy for new, innovative therapeutics and biologics?

- Value-based contracting with manufacturers: 60%
- Use manufacturer net pricing (wholesale acquisition cost plus discounts): 23%
- Adjust the premium costs across the broader pool of members/employees: 5%
- Other*: 12%

*Other responses included: Full pricing and cost transparency based on manufacturer market price or Medicaid floor, prevent manufacturers from using orphan drugs “loophole,” closer monitoring of patient response to medication
Q. What is the best long-term approach to addressing the high cost of rare disease treatment?

46% A more integrated approach by benefit managers around total cost of care across the healthcare continuum

21% Deploying more expansive strategies to assess risk vs benefit with long-term use

15% Government guidelines and/or regulations

14% Use of benefit incentives to drive consumer engagement and higher-value care

5% Other

Q. Should pharmacists be compensated under Medicare Part B for prescribing medications and helping assess patient conditions?

76% Yes

24% No

“I believe that pharmacists should be part of the solution to Medicare Part B costs and prescribing issues, but thus far I don’t believe there has been sufficient research to ‘prove’ the value. Without the proof, the other actors in the system will remain resistant to allowing any of ‘their’ money to be allocated to the pharmacists.”

— Schmidt

Q. Who should play the biggest role in combating the opioid epidemic?

66% Providers

17% Government

10% Payers and PBMs

7% Pharmacists

“I would agree with the readership that providers are the most critical entity in driving change here, as they ultimately serve in the most influential role to affect all aspects of proper opioid risk management. This includes, but is not limited to, properly educating patients; minimizing initial opioid exposure; managing proper continuation or discontinuation of opioid use; promoting alternative therapies; recognizing and proactively managing opioid dependency; and ensuring proper treatment.”

— David Calabrese, RPh, MHP, senior vice president and chief pharmacy officer at OptumRx.

“Combatting the growing opioid epidemic in a lasting and meaningful way will take the efforts of all healthcare stakeholders. Insurers, such as Independence Blue Cross, are key players, not only as repositories of vital health data, but as active partners, working with communities, doctors, hospitals, patients, and their families to improve well-being.”

— Editorial advisor Daniel J. Hilferty, MPA, president and CEO, Independence Health Group
Industry Topics

Q. Which new pharmaceutical approved over the past 12 months are you most excited about?

- 40% CAR T-cell therapies (Kymriah and Yescarta)
- 34% Ocrevus (first approved primary progressive MS drug)
- 18% Luxturna (gene therapy that delivers a functional RPE65 gene to the patient through a viral vector)
- 8% Dupixent (first specialty drug for moderate-severe atopic dermatitis)
- 5% Other

Q. What pharmaceutical in the pipeline—at specialty, new, generic, or other—are you most excited about over the next 24 months?

- 40% Sotagliflozin (oral SGLT inhibitor for T1DM; may be first oral therapy for T1DM)
- 31% Tezacaftor/ivacaftor (cystic fibrosis drug)
- 21% CGRP antagonists (erenumab, galcanezumab, fremanezumab - specialty drugs used for migraine prophylaxis)
- 7% Other

If You Purchased Branded Zymar or Zymaxid Between June 15, 2010 and December 31, 2017, You Could Be Affected by a Proposed Class Action Settlement.


The lawsuit alleges that Defendants engaged in an unlawful scheme to eliminate or delay generic competition for gatifloxacin ophthalmic solution (generic versions of their branded drugs Zymar and Zymaxid), a drug used to treat eye infections, in violation of the Sherman Act. The Defendants have denied all liability in this case and the Court did not decide in favor of the Plaintiff or the Defendants.

Am I A Class Member?
The Class is defined as all persons or entities in the United States who purchased branded Zymar or Zymaxid directly from any of the Defendants between June 15, 2010 and December 31, 2017. For additional details visit the Settlement Website: www.ZymarZymaxidSettlement.com.

How Do I Get A Payment?
If you are a Settlement Class member and did not exclude yourself from the Class, you are eligible to get a payment. If you did not receive a personalized notice of Settlement from the administrator, you need to take action now and download a Claim Form from the Settlement Website or call the Settlement Administrator toll-free at 866-285-5811 to request one. In order to receive a payment, Claim Forms must be postmarked by October 5, 2018.

Your Legal Rights And Options
Exclude Yourself: If you do not want to be included as a Settlement Class member, you must exclude yourself. If you exclude yourself, you get no benefits, but keep the right to file your own lawsuit. To exclude yourself, you must send a letter to the administrator requesting to be excluded postmarked no later than October 5, 2018. The address for the administrator can be found on the Settlement Website.

Object: You can also tell the Court if you do not like any part of the proposed Settlement. To object, you must send a letter that is postmarked by October 5, 2018. For details on how to properly file an objection, please read the detailed notice available at the Settlement Website or call the toll-free number below.

Do Nothing: If you did not get a personalized notice and do nothing, you will get no payment and give up your rights to bring a lawsuit against the Defendants for the legal claims in this case. However, if you received a personalized notice and you are in Defendants’ data, you must submit a Claim Form to receive payment.

Has The Court Approved The Settlement?
No. The Court will hold a Fairness Hearing at 1:30 p.m. on November 9, 2018, at the U.S. District Court for the District of Delaware, 844 N. King Street, Courtroom 4B, Wilmington, Delaware 19801. At the Fairness Hearing, the Court will determine whether the Settlement should be finally approved as fair, reasonable and adequate. It will also determine whether to grant Settlement Class Counsel their request for fees and expenses and any Class Representative awards. Information regarding Settlement Class Counsels’ fees will be posted on the Settlement Website once they are filed with the Court.

This is only a summary. If you have questions regarding this Settlement, visit the website below or call the Settlement Administrator.

866-285-5811
www.ZymarZymaxidSettlement.com
Former Surgeon General C. Everett Coop, MD, famously noted that medications don’t work in patients who don’t take them. No surprise that nonadherence is one of the most prevalent and expensive diseases out there, costing $300 billion in avoidable healthcare spending every year in the United States alone.

“Patients do better when they are adherent; better health, better outcomes, better quality of life,” says Heather Ferrarese, PharmD, owner of Bartles Pharmacy in Oxford, NY.

“Pharmacists know how to talk with patients to understand their barriers to adherence and work through them,” Ferrarese says. “The biggest piece for the pharmacy is just identifying who to engage. Once we know who, it’s easy to start the conversation.”

A recent Research and Markets report came up with more than 60 different products said to boost adherence.

**Smart Pills**

In 2017, the FDA approved the first medication Abilify MyCite (aripiprazole tablets with sensor, Otsuka America Pharmaceutical)

The sensor, developed by Proteus Digital Health, talks with a patch on the torso that sends data to a mobile phone app.

The patch also tracks steps, heart rate, respiration, and sleep activity that provides an accurate pattern of adherence.

The system has been tested with medications for hypertension, heart failure, diabetes, tuberculosis, bipolar affective disorder, and schizophrenia.

**Gift Cards**

Boehringer Ingelheim (BI) rolled out RespiPoints to reward patients who use three of its inhaled products for their healthy behaviors. Points can be redeemed for gift cards at Amazon and Starbucks in return for daily medication check-ins, taking quizzes and surveys, and other activities designed to improve and track adherence.

**Countertop Convenience**

Patients control adherence, which is why HeroHealth created a countertop pill dispenser, Hero. Hero can dispense up to 10 different medications at the proper time of day at the push of a button.

The locked, password-protected device can send an electronic or phone alert for any missed doses.

“I don’t want to know if my mom took her meds, I want to know if she missed them,” says company president Joey Neal.

**Smart Vial**

AdhereTech is one of several companies reimagining the amber pill vial using sensors and communication chips to track adherence. The bottle can flash, play a tune, or send electronic alerts if the patient misses a dose or takes it incorrectly. Data are collected 24/7 by AdhereTech and passed to the pharmacy to intervene.

**Pharmacist Focus**

Pharmacy chains and wholesalers are rolling out proprietary systems to help pharmacists identify patients who are not adherent and intervene. Ferrarese uses McKesson’s Adherence Performance Solution (APS). APS provides daily reports identifying patients who are not adherent based on claims data.

AmerisourceBergen has its community pharmacy adherence toolbox at the Patient Engagement Center and Pharmacy Now. Tools track up-to-the-day performance on Star Ratings medication use measures and identify patients who are underperforming and negatively impacting pharmacy scores.

Cardinal Health uses OutcomesMTM. Originally created as an MTM program administrator, the company has a variety of solutions targeting Part D plans, employers, payers, PBMs, patients and pharmacies.

Fred Gebhart is a contributing editor.
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**MARKETPLACE CAN WORK FOR YOU!**
The FDA has approved betrixaban (Bevyxxa) to prevent venous thromboembolism (VTE) in inpatients at risk for thromboembolic events due to immobility or clinical contributing factors. Current standard of therapy includes subcutaneous heparin or enoxaparin, which may require multiple doses per day. As the only direct oral anticoagulant (DOAC) approved for inpatient VTE prophylaxis, a once-daily oral option avoids the difficulty and inconvenience of giving a dose by injection and can help promote adherence. Betrixaban binds to the active site of factor Xa and inhibits its activity. It inhibits both free factor Xa and prothrombinase activity, which leads to decreased thrombin generation. Betrixaban has no effect on platelet aggregation activity.

Efficacy
Approval of betrixaban was based on data collected from the APEX trial, a randomized double blind multinational study that compared extended duration betrixaban with standard duration enoxaparin in the prevention of VTE in acutely ill hospitalized patients with VTE risk factors. The trial consisted of 7,513 patients who were randomized to receive betrixaban 160 mg orally on day 1 followed by 80 mg once daily for 35 to 42 days or enoxaparin 40 mg subcutaneously once daily for 6 to 14 days.

The efficacy of the trial was measured by a composite score comprised of either occurrence of asymptomatic or symptomatic proximal deep vein thrombosis, nonfatal pulmonary embolism, or VTE-related death. Betrixaban was associated with fewer events (4.4%) than enoxaparin (6%) (relative risk 0.75, 95% CI: 0.61, 0.91).

Safety
In the APEX trial, 54% of patients in the betrixaban group experienced at least one adverse effect compared with 52% of those receiving enoxaparin. The most frequent reason for treatment discontinuation was bleeding, with an incidence rate of 2.4% in the betrixaban group and 1.2% in the enoxaparin group. Severe bleeding occurred in 0.7% of the betrixaban group and 0.6% in the enoxaparin group. Only two cases of intracranial bleeding occurred in the betrixaban group compared with seven cases in the enoxaparin group; and only one major bleeding event that lead to death occurred in both arms. Fewer stroke events occurred in the betrixaban group (0.6%) than the enoxaparin group (1.1%) (relative risk 0.59; 95% CI, 0.35 to 0.97; P=0.03).

Monitoring for signs of bleeding and for concomitant medications that alter hemostasis is important. Therapy should be discontinued in the event of an active hemorrhage. No reversal agent exists for this medication. This medication has a black box warning for spinal or epidural hematomas, which may occur in patients receiving neuraxial anesthesia or undergoing spinal puncture. Other adverse effects from betrixaban are minimal. Side effects include hypertension, headache, hypokalemia, constipation, nausea, and diarrhea.

Dosing and Cost
Recommended dosing for betrixaban is 160 mg orally once daily on day 1, then 80 mg once daily for 35 to 42 days. All doses should be taken with food. There should be a 50% dose reduction for patients with a creatinine clearance of 15 to 30 ml/min or if the patient takes p-glycoprotein inhibitors. This drug should not be used in patients with hepatic impairment. If a dose is missed, the dose should be taken as soon as possible on the same day and then continue the normal schedule on the next day. The estimated out-of-pocket price for a 42-day supply of 44 tablets is about $683.
A bout a dozen pharmacists in my town gather each month for a pharmacy roundtable as part of “Operation Our Town,” which is an initiative formed by businesspeople who want to remove the scourge of drug abuse in our community. A couple of years ago, our local state representative in Harrisburg joined us. John McGinnis, who has a PhD in economics, listened intently while we pharmacists discussed the rescheduling of hydrocodone from Schedule III to Schedule II, and the dramatic price increases we saw. McGinnis asked why the price escalated so much in a brief time, and one pharmacist gave her opinion: Corporate greed.

McGinnis responded that he’s an economist—and didn’t buy that answer. He said blaming such dramatic price increases on corporate greed is like blaming an airplane crash on gravity. He used the Wright brothers as an analogy. When they built their first airplane, McGinnis pointed out that they and every builder since then must factor in gravity, a constant force, into the equation of flying an airplane. Yes, gravity brings it down, he noted, but something failed to allow gravity to take over. McGinnis explained that what he was describing is government interference that caused such price increases. He declared that corporate greed is always a constant, just like gravity. He asserted that corporate greed took over when government interference was present, just like gravity takes over when a malfunction occurs on an airplane bringing it to the ground.

When I see dramatic increases in generic prices on creams and ointments, I’m sure government interference plays a role. [See Cover Story, pg. 9] The U.S. government spent $328.6 billion dollars on prescription drugs in 2016, which is 10% of the total national healthcare expenditure, according to CMS.1 With a pot of money this large, is there any wonder that the price of clobetasol-E cream rose from $10.42 for a 60-g tube to $110, a tenfold increase! Remember when we could buy colchicine 0.6-mg tablets for $6 per hundred, and now we pay $6 per tablet? A 100-fold increase thanks to an FDA ban on unapproved colchicine products.

The one question we pharmacists are most likely to get is, “Are the generics as good as the brand name?” My answer is a resounding yes, with virtually no exception. Last week I pulled a bottle of quetiapine XR 400 mg that cost the pharmacy around $82 for 60 tablets. I still have a partial bottle of the brand name Seroquel XR 400 mg, which costs $1,500. Upon further examination I saw that both were made by AstraZeneca, the company that marketed the brand! Both bottles had tablets with the same markings, the same type and shape bottle, only the label differed. There is absolutely no way anyone from AstraZeneca can explain how a label on the bottle can account for a price difference of more than $1,400.

I was almost nose-to-nose with the head of endocrinology from an area health system, discussing the efficacy of Synthroid versus levothyroxine. The endocrinologist said the brand products are more consistent, which I disagree with. I asked him when he has a patient on Synthroid, does he ever have to change the dose? He said, “Don’t be ridiculous, of course we manipulate doses all the time.” So I said, “You’re telling me the patient is the variable, and not the pills!” He smiled and said, “I guess we will agree to disagree.” If a patient takes their thyroid supplement with food, or worse yet a calcium or iron supplement, absorption will be impaired whether it is brand or generic levothyroxine. The pharmaceutical manufacturers have gotten into the heads of many prescribers!

As Rep. McGinnis stated, “Corporate greed is a constant, just like gravity.”

REFERENCES