INDUSTRY ANALYSIS

Pharmacy Transformation
How a shifting market will change roles

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IMPORTANT SAFETY INFORMATION AND INDICATIONS

Indications
FIRVANQ™ (vancomycin hydrochloride) is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of:
- Clostridium difficile-associated diarrhea
- Enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains)

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

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

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

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

### Adverse Reactions

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

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

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

**Reference:** 1. FIRVANQ™ Prescribing Information. Wilmington, MA: CutisPharma, Inc; 2018.
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)

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

Hypersensitivity to vancomycin

INDICATIONS AND USAGE

FIRVANQ™ (vancomycin hydrochloride) is used to treat or prevent infections caused by susceptible bacteria in the following situations:

- **Infectious diarrhea**: For the treatment of *Clostridium difficile*-associated diarrhea and staphylococcal enterocolitis. Oral administration of vancomycin hydrochloride is not effective for treatment of *Clostridium difficile*-associated diarrhea and staphylococcal enterocolitis. If parenteral vancomycin therapy is desired, use an intravenous preparation of vancomycin and consult the package insert accompanying that preparation.
- **Enterocolitis**: 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.

CONTRAINDICATIONS

- **FIRVANQ™ must be given orally for treatment of *Clostridium difficile*-associated diarrhea and staphylococcal enterocolitis.** Oral administration of vancomycin hydrochloride is not effective for treatment of other types of infections.
- **Parenteral administration of vancomycin is not effective for treatment of *Clostridium difficile*-associated diarrhea and staphylococcal enterocolitis.** If parenteral vancomycin therapy is desired, use an intravenous preparation of vancomycin and consult the package insert accompanying that preparation.
- **Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of vancomycin hydrochloride for *Clostridium difficile*-associated diarrhea.** Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. These patients may be at risk for the development of adverse reactions associated with higher doses of FIRVANQ™; therefore, monitoring of serum concentrations of vancomycin may be appropriate in some instances, e.g., in patients with renal insufficiency and/or colitis or in those receiving concomitant therapy with an aminoglycoside antibacterial drug.
- **Nephrotoxicity has occurred following oral vancomycin hydrochloride therapy and can occur either during or after completion of therapy.** The risk is increased in geriatric patients. Monitor renal function.
- **Otoxicity has occurred in patients receiving vancomycin hydrochloride.** It may be transient or permanent. Assessment of auditory function may be appropriate in some instances.
- **Use of FIRVANQ™ may result in the overgrowth of non-susceptible bacteria.** If superinfection occurs during therapy, appropriate measures should be taken.
- **Prescribing FIRVANQ™ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.**
- **Hemorrhagic occlusive retinal vasculitis (HORV), including permanent loss of vision, occurred in patients receiving 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>
<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>
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<tr>
<td></td>
<td>Abdominal pain</td>
<td>15</td>
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<tr>
<td></td>
<td>Vomiting</td>
<td>9</td>
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<tr>
<td></td>
<td>Diarrhea</td>
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</tr>
<tr>
<td></td>
<td>Flatulence</td>
<td>8</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Edema peripheral</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
<td>5</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Urinary tract infection</td>
<td>8</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Hypokalemia</td>
<td>13</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Back pain</td>
<td>6</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>7</td>
</tr>
</tbody>
</table>

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

In addition to the information presented above from clinical trials, the following adverse reactions have been identified during post-approval use of vancomycin hydrochloride:
- **Ototoxicity:** Hearing loss, vertigo, dizziness, and tinnitus have been reported.
- **Hematopoietic:** Reversible neutropenia, usually starting 1 week or more after onset of intravenous therapy with vancomycin or after a total dose of more than 25 g, has been reported. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocytopenia has been reported.
- **Miscellaneous:** Anaphylaxis, drug fever, chills, nausea, eosinophilia, rashes (including exfoliative dermatitis), Stevens-Johnson syndrome, toxic epidermal necrolysis, and vasculitis have been reported with the administration of vancomycin.
- A condition has been reported with oral vancomycin that is similar to the IV–induced syndrome with symptoms consistent with anaphylactoid reactions, including hypotension, wheezing, dyspnea, urticaria, pruritus, flushing of the upper body (“Red Man Syndrome”), pain and muscle spasm of the chest and back. These reactions usually resolve within 20 minutes but may persist for several hours.

USE IN SPECIFIC POPULATIONS

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

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

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

OVERDOSAGE

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

PATIENT COUNSELING INFORMATION

Antibacterial Resistance:

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

Important Administration Instructions:

- **Instruct the patient or caregiver to:**
  - Shake the reconstituted solutions of FIRVANQ™ well before each use and to use an oral dosing device that measures the appropriate volume of the oral solution in milliliters.
  - Store the reconstituted solutions of FIRVANQ™ in the refrigerator when not in use.
  - 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.
  - 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

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Rev. 2/2018
EDITORIAL ADVISORY BOARD

Editorial Mission: Drug Topics is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
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SPECIAL REPORT
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Community pharmacy’s future hinges on changing the pharmacy payment model. It’s necessary for your continued business success. Attend NCPA 2019 Annual Convention to discover innovative, peer-tested solutions designed to invigorate your practice like:

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- Making Your Mark with Private Label Vitamins and Supplements

Visit convention.ncpanet.org/program for a complete list of business education programs to help you thrive – rather than just survive – in community pharmacy.
Some of the same drug store chains and mail order companies—including Good Neighbor Pharmacy, Sam’s Club, Wegmans, and Humana—continue to rank highest amongst consumers, a new survey finds.

In the J.D. Power 2019 US Pharmacy Study, Sam’s Club ranks highest overall among brick-and-mortar merchandiser pharmacies, followed by Costco and CVS/pharmacy inside Target.

Good Neighbor Pharmacy ranks highest overall among brick-and-mortar chain drug store pharmacies, followed by Health Mart and Rite Aid Pharmacy. Among supermarket pharmacies, Wegmans ranks highest overall, followed by Publix and Winn-Dixie.

In the mail order arena, Humana Pharmacy ranks highest overall, followed by Kaiser Permanente Pharmacy and OptumRx.

“Good Neighbor, Sam’s Club, Wegman’s, and Humana continue to exceed health consumer expectations by consistently executing on behaviors just a little bit more than the rest of the competitive set within their industry,” Greg Truex, managing director of Health

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Intelligence at J.D. Power, tells Drug Topics. “These were the same award winners in 2018.”

The U.S. Pharmacy Study, now in its 11th year, measures customer satisfaction with brick-and-mortar and mail order pharmacies. It is based on responses from 12,059 pharmacy customers who filled a prescription during the three months prior to the survey period of May—June 2019.

While some pharmacies performed very well, CVS ranked lowest among chain drug stores because “they were the only organization that did not improve their customer experience between 2018 and 2019,” Truex says. “All other organizations either remained the same, or their customer satisfaction increased.”

Walmart ranked lowest among mass merchandiser pharmacies because its competitors increased at a much larger rate year over year, according to Truex. “Walmart health consumers were more satisfied in 2019, but their segment just increased at a higher rate,” he says. Safeway was ranked lowest for the second year in a row, but it realized one of the largest year-over-year gains between 2018 and 2019, increasing 18 points. Other key findings of the survey include:

**Face-to-face interaction is still most prevalent.** Most pharmacy customers that communicate with the pharmacist and staff do so in-person (89%), even though customers that use email or online live chat to interact with the pharmacist or staff are equally or more satisfied.

**Thorough pharmacists discussions yield higher customer satisfaction.** Satisfaction with the pharmacist is above 940 (on a 1,000-point scale) when pharmacists cover four or more topics with the customer during their interaction, compared with just one (884) or two (917) topics.

**Health and wellness customers spend more at the pharmacy.** Around two-fifths (42%) of customers who are aware of their pharmacy’s health and wellness services have used one of the services in the past year.

“Vaccinations and flu shots are the most used services by health consumers, followed by health screenings, and treatment for common illnesses. But those services are also cited as lowest in terms of overall satisfaction with health consumers,” Truex says.

While those who have taken advantage of health and wellness services spent 12.5% more on their most recent prescription order, significantly fewer health and wellness consumers received a prescription as a result of their participation in 2019 as compared with 2018.

**Mobile app users are more satisfied, but usage is stagnant.** Only 20% of customers use a pharmacy’s mobile app, but those who did have satisfaction scores as much as 23 points higher than those who do not.

**Vaccines**

**Hepatitis A Declared a Public Health Emergency in Florida**

On August 1st, Scott A. Rivkees, MD, Surgeon General and State Health Office for the state of Florida, declared a public health emergency due to the prevalence of Hepatitis A cases in various counties in the state.

According to Florida’s Hepatitis A Surveillance report released in July, 2,636 cases have been reported in Florida since the start of 2018—2,088 have been reported since the start of 2019. Of those cases, 22% have been linked to other cases, and 24% are co-infected with Hepatitis B or C. Those between 30-39 years of age had the highest incidence of disease.

Since January 2018, 98% of patients that have been diagnosed with Hepatitis A have never received a documented dose of Hepatitis A vaccine, according to the state’s report. As of 2019, 100% of cases have presented in those not having received a documented dose of the vaccine.

Those at risk for contracting Hepatitis A include:

- The homeless
- Intravenous drug users
- Non-intravenous illicit drug users
- Men who have sex with men
- Individuals diagnosed with underlying liver disease
- Individuals in an emergency room or other acute care setting, after being administered an opioid antagonist such as naloxone
- Individuals with clotting factor disorders
- Individuals working with homeless personas or intravenous drug users outside of health care settings
- First responders

Four of the most common methods of contraction listed in the report are via:

- Sexual Contact
- Personal Contact
- Household Contact
- Other/Unknown

Those suffering from chronic liver disease or are over the age of 60 with a serious underlying medical condition are at the greatest risk.

According to Rivkees’ declaration, health-care providers should consider screening for Hepatitis A in patients with non-specific symptoms (fever; chills; malaise; decreased appetite; and/or gastrointestinal symptoms such as nausea, vomiting, diarrhea, and abdominal pain) and symptoms such as jaundice, light-colored stools, and dark-colored urine. Screening should be conducted via liver function tests and transaminase levels.
While new DEA data shows a high volume of opioid prescriptions dispensed via drug stores, the number of opioid deaths has fallen, and pharmacists are working to prevent abuse of painkillers.

Detailed data on distributors and drug store chains was revealed when the DEA’s Automated Reports and Consolidated Ordering System (ARCOS) data was ordered public in a court case.

According to the ARCOS data, 76 billion opioid pain pills were distributed in the United States from 2012 through 2016. Around half of the pills were distributed by three distributors: McKesson (14.1 billion), Walgreens (12.6 billion), and Cardinal Health (10.7 billion), according to CNN.

Despite the high numbers, NACDS President and CEO Steven C. Anderson defended pharmacists’ role in the opioid epidemic. “Every day, pharmacists face a moment of truth when presented with an opioid prescription, making decisions as a provider of patient care and as part of the solution to the opioid-abuse epidemic. Patients understand that community pharmacy is part of the solution, providing trusted advice and quality healthcare services,” Anderson said in a statement.

Pharmacies have a “long-standing and ongoing commitment to working as part of the solution to opioid abuse,” Anderson added.

Despite the DEA data, new numbers from the CDC’s National Center for Health Statistics found a 5.1% drop in opioid overdose deaths between 2017 and 2018.

“The latest provisional data on overdose deaths show that America’s united efforts to curb opioid use disorder and addiction are working,” said HHS Secretary Alex Azar in a statement. “Under President Trump’s leadership, and thanks to efforts on the ground by communities across America, the number of patients receiving medication assisted treatment has risen, distribution of overdose-reversing drugs is up, and nationwide opioid prescriptions are down.”

In addition, drug store chains have implemented several opioid abuse prevention initiatives, including compliance programs, drug disposal, patient education, security initiatives, naloxone access; stopping illegal online drug-sellers and rogue clinics, and philanthropic programs, according to Anderson.

CVS Ramps Up Script Delivery

Soon after announcing it is opening fewer stores and closing some stores, CVS said it is expanding its CarePass membership prescription delivery service nationwide.

In late October, CVS launched the pilot membership rewards program in the Greater Boston area, and then tested it in select markets. For $5 a month or $48 a year, CarePass customers receive free delivery on most medications and purchases, 20% off all CVS Health private label products, and access to a 24/7 pharmacist hotline.

“Initial customer response has exceeded our expectations with members utilizing the program’s full benefits and becoming more engaged across all of our digital offerings,” says Kevin Hourican, executive vice president, CVS Health, and president, CVS Pharmacy. The CarePass membership program includes:

- **Free one-day to two-day delivery on qualifying prescription drug orders and free one-day to two-day delivery for eligible purchases on CVS.com with no minimum order required.**
- **Access to a 24/7 pharmacist helpline.** CarePass members can contact the helpline to speak live with a pharmacist who has secure access to their prescription histories with CVS Pharmacy. “The pharmacist will be able to answer questions about the customer’s medications on-demand and refer them to any additional tools, resources or services that could be helpful,” CVS says.

- **A 20% discount on eligible CVS Health Brand products in-store and on CVS.com**, including OTC medications, vitamins and supplements, as well as personal care items.

- **A monthly $10 CarePass promotional reward that can be used on many items in-store and online at CVS.com.** The CarePass promo reward is automatically added to the customer’s ExtraCare card at the beginning of each monthly cycle and expires at the end of the monthly cycle.

- **Surprise perks and bonus offers at key times throughout the year.** For example, members recently received a complimentary sports physical at their local MinuteClinic. “The program will continue to evolve to include additional services and exclusive offerings in the future,” CVS says.

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Patient-Centered Care, and the Heart of Independents

In this age of big box stores and online retailers, there is frequent discussion about the disappearance of small independent retailers. In healthcare, as consumers’ demands for a more modern and convenient experience grow, industry opinion has focused on the uncertain future of independent pharmacy.

Independent pharmacies are more important—and more central—to the ongoing health and wellness of patients than ever before. As the president of Health Mart, I work hand-in-hand with thousands of independently owned pharmacies across the United States. On a daily basis, I see the innovative patient-centered care that is being delivered that, above all, supports the axiom that “healthcare is local.”

The business of medicine may be global, but healthcare is local. To verify that, all we should do is look at the following statistics from such industry organizations as National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS):

- 95% of Americans live within five miles of an independent pharmacy and these pharmacies dispense nearly half of the nation’s prescription medicines;
- Pharmacists are among the most trusted and accessible of healthcare providers;
- The average patient spends only 20 minutes a year with their doctors, but may go into their local pharmacy once a month or more.
- 75% of independent pharmacies are operating in communities of fewer than 50,000 people

**The first point of care**

Patient expectations about healthcare are changing, which impacts how and where they look to receive care. According to the CDC, the percentage of patients enrolled in High Deductible Health Plans (HDHP) increased from 10.6% in 2007 to 24.5% in 2017 among adults aged 18–64, resulting in higher out-of-pocket healthcare costs. As more financial responsibility gets pushed onto patients, they are increasingly managing their own healthcare decisions by looking for local providers who can deliver diverse clinical services.

When a patient visits a pharmacy, they expect the staff to “care”: to care for their health, and to care about them and their family. As the provider who often serves as the first and last point of care, independent pharmacists’ stores offer an ideal setting in which to provide community-based patient care that is professional, personalized and affordable.

**Supporting the entire patient journey**

Many owners have deep relationships with their local community. It’s not uncommon to meet pharmacists who have served generations of the same families in their town, who keep a 24/7 emergency line that they personally answer, and who have delivered prescription medications at four in the morning to a patient who couldn’t get to the pharmacy on their own.

Pharmacists fill a gap in today’s busy healthcare system by providing health screenings and advice on OTC medicines to treat minor ailments, as well as helping patients manage more serious conditions like diabetes and asthma. To stay healthy, patients can expect additional services, such as immunizations, nutritional support, and other tools delivered in-person at the pharmacy counter and through technology at the patient’s home.

**A bright future for pharmacy**

From my perspective, the endgame for the locally-owned pharmacy is not right around the corner. Despite the changes that are facing all pharmacies, community pharmacies have reasons to be optimistic about the opportunities in the coming years. Pharmacies offer an ideal setting in which to provide patient care that makes a positive impact on medication adherence, improves patient outcomes, and reduces healthcare costs. I remain impressed by pharmacists’ investment in their communities and believe that they are critical to the future of patient care.
Supporting the Value of Independent Pharmacies

By Fred Gebhart, contributing writer

In a competitive industry, businesses that are able to differentiate themselves are able to make the biggest impact. This is particularly true within the pharmacy setting, as industry-wide prescription volume has experienced a 0.4% decline over the past year. However, members of Good Neighbor Pharmacy, a network of more than 3,000 independent community pharmacists, and its PSAO, the Elevate Provider Network, have reported 2.4% year-over-year growth in prescription volume. That compares to a 0.3% loss for non-Elevate independents for the 12 months ending in May 2019.

The numbers come from pharmaceutical data specialists at IQVIA. And they support AmerisourceBergen’s long-time commitment to independent community pharmacy.

“Independent community pharmacy is thriving because they have a unique niche within the retail pharmacy market by providing something very different than the larger pharmacy organizations,” says Brian Nightengale, president of Good Neighbor Pharmacy and senior vice president of Community and Specialty Pharmacy at AmerisourceBergen.

“Independent pharmacies provide a higher touch, higher level of service, more point-of-care testing, more immunizations, more adherence support, and more clinical services. One of the most important things we can do at AmerisourceBergen is help independents tell that story more widely because there are many players that still have the view that a pharmacy is a just pharmacy. We know better.”

The often-unrecognized reality is that independent pharmacies serve higher-cost, more complex patients who choose the high touch personalized experience over mass market alternatives. In fact, in discussions with one major health plan, their data revealed that their most costly patients frequently choose Good Neighbor Pharmacy pharmacies.

“The plan’s question to us, which is very encouraging, was is there something we can do together with Good Neighbor Pharmacy to help move the needle in improving our members’ overall health, which would, in turn, lower the cost to us as a payer? The answer is absolutely yes. Getting that story out to payers, legislators, state insurance commissions, and other stakeholders is absolutely vital for independent pharmacies.”

That advocacy and support task is becoming more streamlined with continuing consolidation in healthcare, Nightengale says. When payers are narrowly focused on pharmacy, hospital, office visits, surgery, and other coverage siloes with high patient turnover, each plan wants only to reduce its own spend. None have responsibility for the overall cost of care. Independent community pharmacists are among the few providers who can help.

“Pharmaceutical care continues to be the most accessible and efficient form of health care in the country today,” says Rich Tremonte, Executive Vice President and President, Community & Specialty Pharmacy at AmerisourceBergen.

“Pharmaceutical care still makes up only 10 to 15% of all healthcare spend in the United States and we don’t see that going up anytime soon. The independent pharmacist plays a critical role in helping patients navigate through their healthcare choices. And knowing that adherence goes down as the out-of-pocket cost of a drug goes up, independent pharmacy becomes even more important as drug costs rise. Nobody has the time, the tools, or the experience helping patients understand the importance of adherence like an independent pharmacist.”

And no other care provider has patient access like an independent pharmacist. The typical patient sees a pharmacist ten times more often than a medical provider, Nightengale notes.

At the same time, providers are increasingly responsible for patient outcomes under value-based reimbursement programs. That responsibility gives providers a positive incentive to work more closely with pharmacists to improve adherence, reinforce lifestyle changes, encourage physical activity, and support other wellness initiatives that contribute to improved outcomes. But, before providers can engage with independent pharmacists, they must recognize the value the partnership can bring.

AmerisourceBergen also advocates for independent community pharmacy with manufacturers, suppliers, and other partners across the supply chain.
Managing asthma is both complicated and costly for patients, so pharmacists play a unique role in helping them navigate how to use their treatments effectively and prevent exacerbations. Keeping up with ever-evolving treatment strategies, guidance, medications, and patient experiences is key.

**New Guidelines**

Guidelines are continually updated to reflect new research, and Cleveland Clinic primary care clinical pharmacist Giavanna Russo-Alvarez, PharmD, BCACP, suggests making it a personal goal to review guidelines annually, and even regularly in between.

“I look for guideline changes,” Russo-Alvarez says. “We as pharmacists can be really helpful in reaching out to practices. We can provide small in-services to keep them informed, as well.”

Sometimes, changes are frequent and clinicians can’t keep up—even with major changes. Russo-Alvarez notes that some clinicians weren’t even aware of a major recent change that shifted decades of asthma treatment.

This change was the recommendation made in April 2019 by the Global Initiative for Asthma (GINA) to no longer treat teens and adults with asthma with short-acting β2-agonists (SABA) alone.

GINA was established in 1993 by the World Health Organization and the National Heart Lung and Blood Institute to improve global asthma prevention and management, and suggested in its latest annual report that teens and adults with asthma should receive symptom-driven or daily inhaled corticosteroid-containing (ICS) treatments as a way to reduce the risk of serious exacerbations.

SABA risks were first identified in the 1980s and 1990s, according to GINA’s annual report, with evidence supporting an association between over-use of SABA and an increased risk of asthma-related deaths. Randomized controlled trials found no evidence to support the efficacy of regular, compared to as-needed, (PRN) use of SABA. Most guidelines were updated in the 1990s to support PRN rather than regular SABA use as a result of this research.

Trials have also shown that low-dose ICS treatment could reduce exacerbations by up to 50% and help control symptoms, but daily uptake of ICS has been slow-going over physicians concerns about the side effects of corticosteroids, according to the report. The concerns about β2-agonists were then shifted to long-acting varieties, and short-acting varieties remained widely used as initial therapy for mild asthma. GINA began looking into the issue more extensively in 2007 and found a host of data to support a link between regular use of SABAs alone, and higher rates of exacerbations and asthma-related deaths.

The paper goes on to list specific treatment recommendations, and Diana M. Sobieraj, PharmD, assistant professor of pharmacy practice at the University of Connecticut, says the new guidelines could result in a shake-up at the pharmacy counter.

“These guidelines recommend against using a SABA as-needed alone, even in the most mild asthmatics. They recommend ICS be used in all asthmatics, even if on a symptom-driven, as-needed basis,” Sobieraj says. “Pharmacists are more likely to see as-needed dosing of ICS with this recommendation, and fewer patients treated with a SABA PRN only. This is very different than what we have traditionally seen for many decades of asthma management.”

**Evolving Treatment Plans**

As if changes to fundamental treatments aren’t enough to keep a pharmacist on their toes, immunotherapy and biologics are changing the game when it comes to treating a host of conditions, including asthma.

Immunology is a developing field in asthma care, with researchers recently identifying genetic variants for all types of asthma that could lead to new treatment modalities. Pharmacists may also see more asthmatic patients being prescribed biologics, particularly for specific types of asthma, Sobieraj says.

“The field of biologics continues to evolve, specifically for patients with what would be considered eosinophilic asthma, which represents a small proportion of asthmatics that are extremely...
difficult to control,” Sobieraj says. “The most recent FDA-approved therapy is dupilumab, which is also approved for steroid-dependent asthma.”

Dupilumab—marketed as Dupixent—was approved by the FDA in October 2018 as an add-on maintenance treatment for patients age 12 and older with moderate- to severe-asthma with an eosinophilic phenotype or who are dependent on oral corticosteroids. The medication inhibits overactive signaling of interleukin-4 and interleukin-13—both of which are proteins that may contribute to the inflammation that causes moderate-to-severe asthma. Dupilumab comes in two doses—200 mg and 300 mg—in pre-loaded syringes, and is given every other week at rotating injection sites after an initial loading dose. Dupilumab has also been approved to treat eczema, and studies are underway for a number of other uses like various allergies and pediatric asthma.

“**At a minimum, pharmacists are really well-positioned to teach patients how to use these inhalers.**”

—GUANNA RUSSO-ALVAREZ, CLEVELAND CLINIC

This newest biologic joins four others already approved for asthma—omalizumab, mepolizumab, reslizumab, and benralizumab—and several more are in development, according to the American Academy of Allergy, Asthma & Immunology (AAAAI). Omalizumab works on the immunoglobulin E (IgE) antibodies that play a role in allergic asthma; and mepolizumab, reslizumab, and benralizumab all target pathways that affect eosinophils—the cell involved in allergic inflammation.

**Patient Education, Exacerbation Prevention**

Pharmacists are the front line to helping keep patients—particularly in the outpatient setting—compliant with their regimen, or signal to the clinician when a patient’s condition changes.

“I make sure I have a good understanding of what’s been happening recently with patients,” Russo-Alvarez says. She asks about recent changes like hospitalizations and exacerbations to guide her assessment and the questions she asks her patients. Ask about devices—patients may be using them at the wrong time or in the wrong way. Russo-Alvarez suggests asking both new and long-standing patients to demonstrate how to use inhalers, letting them lead the demonstration. It’s surprising what you can learn by watching a patient use a device, and asking the right questions, she says.

“At a minimum, pharmacists are really well-positioned to teach patients how to use these inhalers,” Russo-Alvarez says, adding that sometimes providers don’t have inhalers on hand to teach patients about their use, or patients become confused on how and when to use different types of inhalers.

She recommends using an inhaler technique training and assessment tool, which can mimic different types of inhalers.

“It can be set to mimic what breathing technique is used in soft mist versus dry powder and metered-dose inhalers,” she says. “You can use it to get feedback on how they are breathing, and the pharmacist can see what works best for the patient and reach out to the provider and maybe recommend an alternative, if needed.”

Pharmacists are also crucial in signaling to clinicians when there may be a change in a patient’s condition. According to Russo-Alvarez, it is a red flag when patients are filling their rescue inhalers frequently, despite using them correctly.
For decades, generic drugs were an effective and less costly option for patients, but new changes in the market are making it more difficult than ever for generics and biosimilars to successfully compete on formularies.

“Generics are a threatened species right now and that goes double for biosimilars,” says Louis Tharp, executive director and co-Founder of the Global Healthy Living Foundation and CreakyJoints.

Experts note a significant shift in the marketplace that has led to more generic drugs getting placed on higher formulary tiers—significantly increasing copay amounts for patients. Branded manufacturers also deploy a series of strategies, such as the use of rebates, to try to limit the reach of new generic products.

“Generally, what we have been observing and hearing from members are increasing challenges in terms of formulary access, both with respect to older commoditized generics and newer generic launches,” says Craig Burton, vice president of policy for the Association for Accessible Medicines.

**Fewer Generic Drugs on Tier 1.**

Research has shown a significant drop in the number of generic medications being placed on the lowest formulary tiers in recent years. Some believe the trend is driving up patient costs and making it increasingly difficult for generics to compete.

According to a recent Avalere survey examining Medicare Part D trends of generic drugs, researchers found that in 2011, 71% of generic drugs were placed on tier 1; but by 2015, only 19% of covered generic drugs were placed on tier 1. It was much more likely in 2015 that generic drugs would be placed on tier 2 (46%) or tier three or higher (35%).

This 53% drop in the number of drugs placed on the lowest tier also translated to a $6.2 billion increase in the total patient cost sharing for the same drugs.

One potential reason for the significant jump in patient cost-sharing could have been attributed to increased utilization; however, Avalere found that during this time period utilization only increased by about 20%. In addition, the price of generic drugs assessed only increased by 1% during the same period.

“The result was pretty clear—this is simply plans shifting generic drugs to tiers with higher copays, mixing them in on branded drug tiers with higher copays and seniors not receiving the full value of those generics,” Burton says.

Just this year, Avalere released a new analysis of Medicare Part D generic trends and found that between 2016 and 2019, generic drugs were placed on the
lowest tier 14% of the time.

Burton says since research seems to indicate that the trend of placing generic drugs on branded tiers with higher copays does not appear to be driven by the price of generics, the association has had to consider other possibilities for the change in practices.

The emerging assumption is that higher brand drug costs are driving greater co-pays across the board, he says.

A 2019 Johns Hopkins University study published in *JAMA Internal Medicine*, analyzed 57 Medicare Part D formularies and found that 72% placed at least one branded drug in a lower cost-sharing tier than its generic product. In addition, 30% of the formularies adopted fewer utilization controls on the branded product compared to its generic counterpart.

“That should be economically impossible,” Tharp says.

**Entrance Challenges**

Older generics aren’t the only ones finding it difficult to compete in today’s marketplace. New generic or biosimilar launches are also finding it difficult to gain a share of the market—often due to brand rebates that drive down the overall cost of a branded competitor.

“A number of new generic launches are seeing significant challenges to even being available to patients because they are being excluded from formularies presumably as a result of brand drug rebate agreements that are conditioned on the exclusion of the generic competitor,” Burton says.

In general, he says one of the problems is the lack of transparency about what happens to rebate money or what effect these rebates really have on formularies.

Lack of access may be hindering medication affordability—a problem for high-cost conditions, such as diabetes. According to the American Diabetes Association, three follow-on biologic insulins have been approved by the FDA, and two are available for sale in the United States. These drugs are priced about 15% lower than their original version; however, none of the follow-on biologic insulins have been approved as substitutable or interchangeable, making their use more difficult.

“The ADA recommends the FDA continue its efforts to encourage additional competition within the insulin landscape, including fostering biosimilar competition,” they wrote in a public policy statement addressing the rising costs of insulin and strategies to lower insulin costs.

**Increasing the Ability To Compete**

The FDA announced steps to encourage biosimilars and more affordable brand insulin starting in 2020, but according to a white paper released by the Biosimilars Council, several barriers need to be addressed that could limit patient access to biosimilar insulin forms.

To improve biosimilar access to formularies, the council recommends that policymaking by the FDA, CMS, and Congress should ensure that rebates and “formulary gamesmanship” doesn’t prevent patient access to biosimilars. In addition, removing regulatory barriers to competition, rethinking the use of rebates and increasing patent transparency could aid in improving competition, the council contends.

Burton says the Association for Accessible Medicines has proposed several possible steps to CMS that could improve generics access to formularies. For instance, the association believes that generics should automatically be placed on generic tiers when they are launched and should no longer be co-mingled on tiers with branded drugs.

Tharp says it’s important to remember that PBMs are simply trying to succeed in the capitalist system the country has created.

“There aren’t any solutions to this,” he said. “We have to sit down and seriously change the structure, and in the process, we cannot kill insurance companies, drug companies, PBMs, hospitals, (or) doctors.”

Tharp believes policy efforts that make sweeping moves to eliminate rebates entirely—like the proposal by President Trump to eliminate drug rebates in Medicare and Medicaid—fail to take into consideration the complexity of the current system.

“You can’t just say the rebate rule is gone because that’s a major profit center for PBMs. In the current system we need PBMs, and they are only doing what the system allows them to do,” he says.

Trump’s proposal was withdrawn in July after receiving significant backlash from insurers and hospitals.

Although it may not be easy, Tharp says he remains optimistic that if the country as a whole slows down and reconsider its current healthcare philosophy, it may be possible to reverse current trends and once again appreciate the value that generics can play in the marketplace.

**Drugs Topics** reached out to CVS Caremark, Express Scripts, and Optum RX to try to learn more about how PBMs made their formulary decisions, but did not receive a response.

**“We have to sit down and seriously change the structure, and in the process, we cannot kill insurance companies, drug companies, PBMs, hospitals, (or) doctors.”**

—LOUIS THARP
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1. Analysourc Report 2019, August 29, 2019; Authorized Generic Indicator Analysis
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Excerpt from FDA statement regarding Authorized Generics:

*An authorized generic drug is the same as the brand-name drug but does not use the brand name on the label. In addition, an authorized generic version of a tablet or capsule may have a different color or marking. Because an authorized generic drug is marketed under the brand name drug’s New Drug Application (NDA), it is not listed in FDA’s Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book). An authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is the same drug.*

1 FDA.gov - Search: FDA List of Authorized Generic Drugs (updated 12/27/2018)
Biosimilars: Examine Access and Cost

By Mari Edlin

Despite the passage of the Biologics Price Competition and Innovation Act of 2009, which provided a regulatory pathway for biosimilars, only 20 have been approved, and seven marketed, in the United States. The most recent was Kanjinti (trastuzumab-anns) for Herceptin (trastuzumab).

IQVIA expects biosimilars to lower overall spending on biologic medicines by $153 billion from 2019 to 2023 as a result of competition.

A study conducted by Avalere Health found that the availability of biosimilars could increase overall access to biologic medicines by an additional 1.2 million patients.

Slow Development, Launch of Biosimilars

“Developing and marketing biosimilars is an expensive proposition. It takes a significant investment in manufacturing expertise and a capacity to create these types of drugs,” says Steven Lucio, PharmD, vice president of pharmacy solutions for Vizient Inc.

“In addition, the biosimilar approval process has taken some time for the FDA to build. Therefore, manufacturers have had to work on various aspects of development while FDA was making final decisions,” he says. “Now that the FDA and manufacturers have worked through 20 approvals, there is a greater level of awareness of what is required to be successful with this type of drug development.”

Kevin Nelson, a partner within the Generic and Biosimilar Pharmaceuticals Practice Group at Schiff Hardin in Chicago, attributes slow development in part to companies’ initial wariness of proceeding down the biosimilar pathway due to the amount of uncertainty associated with the process. He is optimistic, however, that application approvals are rising due to more guidance on the technical front, a better understanding of the considerations related to biosimilar litigation, and higher acceptance in the marketplace.

“The FDA does a good job with guidance; but, from a regulatory perspective, not many [biosimilars] have been approved or launched. The marketplace for biosimilars is not where it is expected to be by 2019,” says Juliana Reed, vice president of corporate affairs for Pfizer.

Targeting Misaligned Incentives

The Biosimilars Forum—an organization based in Washington, D.C.—has developed three proposals for promoting the use of biosimilars and for countering misaligned incentives and unfair reimbursement:

1. Lower costs by eliminating a copayment for Medicare beneficiaries who choose a biosimilar.

2. Develop a physician-focused, shared savings program in which Medicare savings associated with prescribing a biosimilar is shared with providers.

   Not only would that provide an incentive for providers but it could save as much as $3 billion in tax dollars over 10 years.

3. Increase add-on payments for prescribers of biosimilars to incentivize their use by increasing the amount doctors in Part B are reimbursed for administering them.

The Forum estimates that would save patients $3.3 billion dollars in out-of-pocket costs over 10 years and save taxpayers $5.2 billion.

Patents

Patent walls are one of the greatest barriers preventing biosimilars from entering the marketplace. Drug companies could create patent walls around their
products by changing manufacturing processes, finding new indications for an approval, or by changing a drug’s dosage—all extending protection over a long period of time.

Jeffrey Hausfeld, MD, chairman of the board and chief medical officer for BioFactura in Frederic, Maryland, says that although the goal of a biosimilar is to produce a drug identical to its reference, interchangeability is considered bumping up against a patent if both products are exactly the same.

Hausfeld says AbbVie holds about 136 patents for Humira (adalimumab), while the first biosimilar alternative isn’t due to hit the U.S. market until 2023.

The Physician Perspective

"The whole concept of biosimilars is completely new to providers. As a result, pharmacists, as drug information experts, have had to invest a lot of time to learn the nuances of the FDA’s approval process in order to educate prescribers, who are still becoming familiar with biosimilars and developing the necessary level of comfort to prescribe them to patients,” Lucio says.

Another challenge for providers, he says, is when a doctor selects a product (i.e., a biosimilar) different from what a payer chooses (i.e., the reference product or another biosimilar).

“When this happens, both parties have to do more work to manage the information exchange regarding which product will be used and reimbursed. For providers, the need to respond to various decisions across a range of payers could mean they have to carry multiple products (the brand and several biosimilars),” he says.

Lucio says the willingness of physicians to use biosimilars varies by agent. For example, physicians have been less reticent to prescribe Zarxio (filgrastim-sndz)—biosimilar to Neupogen (filgrastim)—because it is easy to monitor, is administered daily, and presents immediate outcomes.

On the other hand, Lucio says biosimilar competitors, such as Inflectra (infliximab-dyyb) for Remicade (infliximab) are facing less uptake because their effect is harder to assess and reimbursement is more difficult to align.

Len Arsenault, vice president of policy, medical and external engagement at Sandoz Inc., says the U.S. healthcare system saved about $500 million in less than two years through the adoption of its biosimilar Zarxio. The product has become the first of its kind to surpass its reference biologic in market share. According to real-world data from Sandoz, patient costs for Zarxio were 9% lower than those for its reference biologic.

Interchangeability

In May, the FDA published its Guidance for Industry entitled, "Considerations in Demonstrating Interchangeability With a Reference Product." The guidance describes the regulatory pathway for biosimilars that can be substituted, without the involvement of a prescriber, for branded biologics. It assists in demonstrating that a proposed therapeutic protein product is interchangeable with a reference product for the purposes of submitting a marketing application.

Without the option of interchangeability, biosimilar manufacturers are forced to compete with established products, which can add costs that are borne ultimately by the consumers,” Nelson says.

“Because there are no approved interchangeable biosimilar products on the market, patients will not receive an approved biosimilar if they are currently on therapy. There is no mandatory substitution at the pharmacy level as there is with small molecule products,” Nelson says.

He advocates for investigating a statutory change that requires treatment-naïve patients—those that have never received the particular biologic product in any form—to receive an approved biosimilar or the lowest-cost option of the prescribed product. Other proposals include creating a separate tier exclusively for generics and biosimilars, and for a cost-sharing program.

Lucio doesn’t find interchangeability to be a real issue because the majority of competitive products are administered by a provider or through specialty pharmacy and not filled by a patient; thus, the pharmacy is not making a decision on which product to use. However, in the case of insulin, patients pick up their prescriptions at a pharmacy, making the choice of a biosimilar more relevant.
**The Naming Conundrum**

Naming biosimilars—the branded drug’s name and a unique, four-letter suffix—is a bone of contention among biosimilar advocates. The Biosimilars Council has urged the FDA to reverse course on its current proposal and rescind the suffix-based naming policy that serves as a barrier to biosimilar access for America’s patients.

The Council asserts that suffixes could create a perception that there are meaningful differences between reference products and their biosimilars, along with patient and provider confusion because reference products don’t require a suffix. It also contends that suffixes could undermine interchangeability and fail to signify any safety benefits. A final ruling has not yet been issued.

**Rebates’ Role**

More than 90% of employer-sponsored plans covered a biosimilar of filgrastim in 2017, and more than 40% placed it on a preferred tier, according to the Institute for Patient Access; however, only about 7% had a biosimilar for infliximab on a preferred tier, according to Avalere.

“The issue is paying for them: the complex reimbursement process for biologics and biosimilars often disincentivizes the prescribing and use of biosimilars,” Nelson says.

“Biosimilars certainly have not achieved the tiered formulary status that is seen by generic drugs in the small molecule space. Due to the pricing and reimbursement system, a provider is sometimes reimbursed at a lower rate for using a biosimilar than for using the reference biologic—a disincentive to prescribing a biosimilar,” Nelson says.

“In the private sector, payers will reimburse based on a percent mark-up of the ASP of the drug that is actually administered. Because the ASP for a biosimilar is lower than that of the reference product, purchasers would prefer to use the more expensive reference biologic for which they could make more money on the mark-up,” Nelson says.

Pharma companies are in litigation due to insurer-directed biosimilar exclusion contracts which opponents argue the practice is restricting entry and competition.

UnitedHealthCare covers Neulasta (pegfilgrastim) first, and if it proves ineffective, then the insurer will cover its biosimilar, Udenyca (pegfilgrastim-qbv). That is opposite of how it works for traditional generics in which a patient must fail on a generic before being given a brand name drug.

“It’s not medically sound to fail first with a reference drug before being able to access a less expensive biosimilar,” Reed says.

“If the reference product doesn’t work, the biosimilar probably won’t either,” Lucio says.

“Biosimilars create a more competitive pricing environment among drug manufacturers that can help drive down drug costs. UnitedHealthcare evaluates each brand-name biologic and its biosimilar one-by-one and makes a coverage decision based on the lowest cost product in order to deliver lower costs to our members, clients and consumers,” says the insurer.

**New Medical Pharmacy Solutions**

Magellan Rx Management has launched a medical pharmacy solution targeting oncology biosimilars. As an expansion of its program focusing on autoimmune biosimilar, Magellan’s solution will include incorporating biosimilars into key utilization management programs; educating network oncologists; and relying on insights from its oncology advisory board and other industry experts.

Magellan anticipates a savings of $5 million to $8 million per one million covered lives based on $50 million in annual drug spend per one million lives for the three oncology brands likely to be available as biosimilars in 2019.

Its promotion of biosimilar versions of Remicade (infliximab) to treat autoimmune diseases increased use to 86% in the first year, resulting in 34% savings in drug costs.
Biosimilars: Some Call for ‘Cautious Optimism’

By Daniel Verdon

While there is debate about the size of the U.S. biosimilars market and its ability to trim drug costs overall, a leading consulting group calls for ‘cautious optimism’ about biosimilars potential to reduce costs.

The Advisory Board’s Lindsay Conway, managing director of Pharmacy Executive Forum, and Pam Divack, an analyst of Life Sciences, say that the successful evolution of the biosimilar market is going to take “targeted efforts to alleviate legal, regulatory, and operational hurdles.” The Advisory Board team made the comments following two high-profile Wall Street Journal op-ed pieces by Peter Back, director of the Drug Pricing Lab at Memorial Sloan Kettering Cancer Center and Mark Trushheim, of the MIT Sloan School of Management. That was followed by a rebuttal on the future of biosimilars by former FDA Commissioner Scott Gottlieb.

The Advisory Board opted to emphasize two key issues surrounding the success of biosimilars, including:

- **The U.S. biosimilars market still needs time to develop.** Gottlieb’s point is that it took more than 20 years for generic small-molecule drugs to capture 87% market share. Therefore, more investment in research and physician education is extremely important.

- **The U.S. healthcare industry can learn from Europe’s gains in efficiencies.** “Any lessons or scale efficiencies we can glean from global markets seem worthwhile, and, even more so, are likely to advance efforts toward broader U.S. adoption and lower biosimilar prices,” Conway and Divack say. Successes noted in Europe lead to other relevant questions too.

  - What if we could lower the cost of biosimilar development by sharing (and accepting) trial data with other countries?
  - What if their real-world evidence can expedite our learning about bioequivalence, matching the right patient to the right treatment, and appropriate use?
  - Could we replicate their best practices for educating physicians about biosimilars and safeguarding against prescribing errors?

“Biosimilars create new financial, operational, and patient safety considerations—all of which must be addressed to ensure adoption,” Conway and Divack say.

“Perhaps the most significant is inconsistencies in payer coverage. While some insurers have expressed preference for biosimilars, given their lower list prices, they have made coverage decisions on a drug-by-drug basis in practice (seemingly based on rebates or other arrangements with the drug manufacturers). As a result, providers must factor individual patients’ coverage into prescribing decisions or they risk losing reimbursement and saddling patients with unaffordable costs.”

For more information and access other posts on biosimilars and generics, go to www.advisory.com/daily-briefing/2019/09/05/biosimilars.

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**BIOSIMILARS APPROVED IN 2019**

**ONTRUZANT** (trastuzumab-dttb); Reference Product: Perjeta, Genentech

HER2/neu receptor antagonist for HER2 overexpressing receptor antagonist for HER2 overexpressing breast cancer, metastatic gastric or gastroesophageal junction adenocarcinoma.

**TRAZIMERA** (trastuzumab-qyyp); Reference: Perjeta, Genentech

**KANJINTI** (trastuzumab-anns); Reference: Perjeta, Genentech

**ETICOVO** (etanercept-ykro): Reference: Enbrel, Amgen

Tumor necrosis factor blocker for rheumatoid arthritis, polyarticular juvenile idiopathic arthritis in patients aged 2 years or older, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis in patients four years or older.

**ZIRABEV** (bevacizumab-bvzr); Reference: Avastin, Genentech

Vascular endothelial growth factor inhibitor indicated for various cancers. See prescribing information for specifics.

**RUXIENCE** (rituximab-pvvr); Reference: Rituxan Hycela, Genentech/Biogen

CD20-directed cytolytic antibody for Non-Hodgkin’s Lymphoma, Chronic Lymphocytic Leukemia, or Granulomatosis with Polyangiitis.

**HADLIMA** (adalimumab-bwwd); Reference: Humira, AbbVie

Tumor necrosis factor indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult Crohn’s disease, ulcerative colitis, and plaque psoriasis.
Generics of Older Drugs Could Have Saved Medicare Billions, Study Says

Findings suggest that racemic substitution for single-enantiomer drugs offers an opportunity for savings

By Tricia Krizner

Medicare and its beneficiaries could have saved an estimated $17.7 billion over a seven-year period on generic versions of older medicines instead of paying for newer, chemically similar but more expensive brand-name drugs, according to a study published in the *Annals of Internal Medicine* last month.

The study was conducted as part of the Collaboration for Research Integrity and Transparency at Yale Law School, funded by the Laura and John Arnold Foundation. The intent was to estimate the potential savings associated with using racemic precursors instead of their single-enantiomer versions to the Medicare Part D drug benefit program and its beneficiaries.

Between 2011 and 2017, Medicare and beneficiaries could have saved the $17.7 billion through substitution of 12 single-enantiomer drugs with their racemic precursors. Substitution of armodafinil for modafinil would have actually increased Medicare spending, but substitution of esomeprazole for omeprazole accounted for more than three quarters of the total estimated savings, and approval of generic esomeprazole in January 2015 contributed to an approximate 20% decline in total savings from 2015 to 2017 when compared with 2012 to 2014.

The study analysis was limited to the seven-year period, which is only a partial amount of the time that these drugs have been available, and does not take spending by Medicare Advantage plans into consideration.

Researchers could not account for actual rebates, which for some branded drugs (including esomeprazole), may be substantially higher than 26.3%, the highest rebate reported by Medicare for any therapeutic class in 2014.

The authors, led by Alexander C. Egilman, BA, assumed that there was complete substitution of racemic precursors, although patient-specific risk–benefit considerations will influence drug choice, and not all substitutions would be clinically appropriate.

Finally, savings vary depending on several factors, such as beneficiary income status and Part D plan benefit structure, as well as future market entry of generic single-enantiomer drugs. Nevertheless, while $17.7 billion is only 2.1% of total Medicare Part D spending from 2011 to 2017, the study findings suggest that racemic substitution for single-enantiomer drugs offers an opportunity for Medicare drug savings.
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Multiple sclerosis (MS) is a chronic inflammatory condition that affects the central nervous system (CNS), and it can result in significant disability and death. According to the American Academy of Neurology (AAN), more than 2.3 million people are living with MS worldwide, and disease-modifying therapies (DMTs) are considered the mainstay of therapy to help to reduce the frequency and severity of relapses. However, these medications are also associated with adverse effects ranging from mild to life-threatening. Current phase 3 studies are investigating new ways and novel approaches to prevent MS relapses.

Healthcare executives are concerned about the cost, quality, and outcomes of MS drugs, making it a top priority for patient care and expenditures. According to a study published in Neurology, out-of-pocket monthly costs for MS medications increased from approximately $15 to about $309 over 12 years. According to the National Multiple Sclerosis Society, the average median price of MS DMTs in 2013 was less than $60,000 while the price in 2018 was $80,000. Patients with MS also face co-insurance that could be as high as 40%, which translates into a monthly cost of over $2,500 for their DMTs.

Legislation that makes MS medications more affordable is needed to alleviate patient costs. Healthcare professionals can play an important role through an interdisciplinary approach to managing patients with MS and identifying financial options such as patient assistance programs to alleviate costs.

**Phase 3 MS drugs in the pipeline**

Erin Lopata PharmD, MPH, senior director, Access Experience Team at Precision for Value points out that Tecfidera (dimethyl fumarate) is approaching the end of its patent exclusivity, and there are several similar medications that are anticipated for FDA drug approval. Lopata adds that Vumerity (diroximel fumarate) is a produg for monomethyl fumarate, which is the active metabolite of Tecfidera and may cause less gastrointestinal adverse events.

Interim efficacy and safety results from the Phase 3 EVOLVE-MS-1 study were recently presented at the AAN Annual meeting, and showed that after 48 weeks, relapse rates decreased by about 79% relative to baseline. Biogen has submitted the new drug application (NDA) and approval of Vumerity is expected sometime in 2019.

Banner Life Sciences has received tentative FDA approval for Bafiertam (monomethyl fumarate) for relapsing forms of MS. Lopata discussed that Bafiertam is the active metabolite of both Tecfidera and Vumerity, and its launch is anticipated for June 2020. Celgene has submitted its NDA for ozanimod for the treatment of adults with relapsing forms of MS. The FDA previously rejected the NDA based on insufficient data, but it is expected to receive approval based on the new submission on March 25, 2020. Data is based on the SUNBEAM and RADIANCE trials, which demonstrated that ozanimod was effective at preventing MS relapses.

Ozanimod is an oral sphingosine 1-phosphate (S1P) receptor modulator. “With a mechanism of action similar to the recently approved Mayzent (siponimod) and an optimal pharmacokinetic profile, ozanimod hopes to demonstrate an improved safety profile to Gilenya (fingolimod),” says Lopata. Ozanimod has only been studied in relapsing forms of MS; however, Mayzent is FDA approved for both relapsing and secondary progressive populations.

“With the success of Ocrevus (ocrelizumab) for MS, additional CD20-directed monoclonal antibodies are likely to follow,” says Lopata.

Another candidate on the horizon is ublituximab (TG-1101), which is being studied by the biopharmaceutical company TG Therapeutics. Ublituximab is a monoclonal antibody that targets the CD20 antigen, and anti-CD20 antibodies have been shown effective in treating various conditions including MS. The company recently announced phase 2 data at the AAN annual meeting showing that the drug is well tolerated. Phase 3 trials known as Ultimate 1 (NCT03277261) and Ultimate II (NCT03277248) are currently being conducted to assess the safety and efficacy in patients with relapsing MS.
New Video Marketing Tools

With more than a billion users on YouTube now, according to the company’s statistics page, ensuring your pharmacy’s video marketing dusts the competition has never been more important.

Michael Miller, author of “YouTube for Business,” agrees: “This represents one of the biggest marketing opportunities in a long time. If you’ve never visited the YouTube website, you’ve missed out on the hottest thing on the internet today.”

Alex Anderson, general manager of Oswald’s Pharmacy, is a big believer in the marketing medium. “We try to put out a new video every month or two to engage our followers online,” he says. The pharmacy’s most popular video so far is a how-to for compression socks (bit.ly/2TQykPK). “We also have reels out on the hottest thing on the internet today.”

Blair Thielemier, PharmD, founder of Consultancy network PharmapreneurAcademy.com, says “web video should be part of your overall marketing strategy because of its versatility. Pharmacy owners who are doing well with video are doing behind the scenes clips—tip videos—showing off products they recommend, and celebrating special days or community events they’re involved in.”

“The biggest thing to remember with any type of video marketing is having a strong call to action. This would be like a free consultation call for a new program you’re launching or joining your pharmacy’s email list,” Thielemier says.

Fortunately, there has been onslaught of new video marketing tools cropping up on the market, which can ensure your pharmacy will stay a step ahead of the competition when it comes to dazzling current and prospective customers.

Here’s a representative sampling of some of the newest and most innovative tools:

**Wochit**
(wochit.com), call for pricing
This is a video editing solution with an interesting spin: Simply feed Wochit an article or other piece of text, and it will automatically roam the web to find licensed photos, videos, and graphics that go along with that text.

Currently used by a number of global news outlets to quickly generate videos from their articles, Wochit also offers a drag-and-drop canvas you can use to quickly drop in the photos, videos, and other graphics it finds, so you can finish a video in record time.

**VideoScribe**
(videoscribe.co), $29/month
Instead of spending hours trying to animate a still image, let VideoScribe do all the animating for you. Indeed, any image you place on its VideoScribe’s canvas is instantly animated. You can finish your video project with other tools in VideoScribe’s arsenal, including voice-over recording, soundtracks, and call-to-action elements.

**Microsoft Video Indexer**
(vi.microsoft.com), free
Video Indexer is designed to automatically analyze the video library you’ve put together for your pharmacy and make it instantly searchable.

With Video Indexer, you can use a few keywords to find videos in your video library featuring those words spoken in a video. Plus, you can find images of a certain person, images of two people who have appeared together, etc.

**Vyond**
(vyond.com), call for pricing
This is a perfect program for pharmacies looking to tell a story with animated characters.

Enabling you to create animated videos using simple drag-and-drop tools (think colorforms on steroids), the program can automatically sync narration to go along with the animated characters you pick for your video.

Vyond also has access to tens of thousands of animated images you can use. And it offers you the ability to import your own audio, images, and video.

For an in-depth look on how the program works, check out Vyond’s YouTube Tutorials (bit.ly/2oGbA3w).

Similar animation products include:
- PowToon (powtoon.com),
- Animaker (animaker.com),
- Moovly (moovly.com),
- Renderforest (renderforest.com),
- Google Web Designer (google.com/webdesigner),
- Explee (explee.com).

**StoriesAds.com**
(storiesads.com), call for pricing
If you’re having trouble getting videos up on Instagram, StoriesAds can help. It’s specifically designed to make producing videos for distribution on Instagram a snap and it is also equipped with easy-to-use drag-and-drop tools to streamline the whole experience.

**Avid Media Composer | First**
(avid.com/media-composer-first), free:
AMC First is the lite version of the already existing—and extremely high-powered video editor—Avid Media Composer. The premium version is a tool regularly used by TV shows and other video producers in Hollywood, but the lite version is still plenty powerful. Essentially, the lite version is designed to enable you to quickly piece together layers of video, dialog, music and sound effects to produce captivating, professional-quality video content for your pharmacy.
The Latest Autoimmune Disease Treatment Advances
The state of some of the costliest diseases

By Keith Loria

Science and technology have drastically improved how autoimmune diseases are managed, and there are more options than ever before to treat autoimmune diseases.

Chase Spurlock, PhD, professor at Vanderbilt University and CEO of IQuity, a Nashville-based analytics startup offering an autoimmune disease-focused data analytics platform, says for many autoimmune diseases the available treatments can effectively control disease, but there is no one-size-fits-all approach.

He adds that all too often, patients are wandering through the healthcare system trying to find answers and some patients receive the wrong diagnosis and are placed on medicines that are not only expensive but also carry a high level of risk. Receiving an accurate diagnosis as quickly as possible is vital to ensure for the best long-term outcomes.

"Time is of the essence. If autoimmune diseases are allowed to progress without any therapeutic intervention, irreversible tissue damage and disability ensue," he says. "We are very fortunate to live in an era where the therapies to treat many autoimmune diseases are highly effective, especially if they are prescribed early."

Here are some of the latest advancements for autoimmune disease diagnoses and treatments.

Psoriasis
Psoriasis is a common autoimmune disease that affects more than 8 million people in the United States and has a significant burden on patients’ quality of life. Patients are often faced with embarrassment because of the visible plaques on their skin and some patients isolate themselves for fear that others will think their disease is contagious.

In the summer months, this is especially important because clothing worn in warmer weather tends to expose more skin and therefore more unsightly plaque.

Fabrice Chouraqui, president of Novartis Pharmaceuticals Corp., says the treatment of psoriasis has been evolving over the years and there are now multiple therapeutic options.

"Cosentyx is the first and only fully human IL-17A antagonist which has demonstrated efficacy in moderate to severe plaque psoriasis, which may involve troublesome areas such as the nails, the scalp, hands and feet," he says. "When these areas are involved, psoriasis has an even greater impact on a patient’s quality of life. Cosentyx has also shown efficacy in the joints and is approved for active psoriatic arthritis and active ankylosing spondylitis."

Unlike some other therapies that have only shown efficacy in the skin, Cosentyx is also a proven therapy for psoriatic arthritis, which is a complication of psoriasis that can cause irreversible bone damage and disability.

The Institute for Clinical and Economic Review (ICER) recognized that IL-17 agents provide long-term value to insurers, patients, and the healthcare system. ICER’s 6/18 Psoriasis Update Evidence Report reviewed Cosentyx and other targeted immunomodulators for moderate to severe plaque...
psoriasis and concluded that first-line treatment with IL-17 drugs is a reasonable strategy due to their high efficacy and reasonable economic value, even in comparison to step therapy using a less effective and less expensive targeted drug first line.

Chouraqui said Cosentyx costs virtually nothing for a 30-day prescription with the Novartis $0 copay program for those with commercial or private insurance.

In April, the FDA approved Duobrii (halobetasol propionate and tazarotene), a lotion developed by Bausch Health, which contains two medications for the treatment of plaque psoriasis in adults. The medicines work together to slow the growth of skin cells and reduce the symptoms of plaque psoriasis.

Additionally, the FDA recently approved Sorilux Foam (calcipotriene, Mayne Pharma), a topical treatment originally indicated for adult patients only, as being safe for pediatric patients 12 and older.

**MS**

A study led by Dr. Mitchell T Wallin of the Department of Veterans Affairs MS Center of Excellence and Georgetown University, and supported by the National Multiple Sclerosis Society, revealed the prevalence of MS in the U.S. is nearly 1 million people, more than twice the previously-reported estimate. This suggests many more people are living with MS than previously thought, and in particular the number of people with a progressive form of the disease—where the greatest needs continue to exist—may be much higher as well.

"This study tells us many things, but one thing in particular—twice as many people need a cure," says Cyndi Zagieboylo, president and CEO of the National Multiple Sclerosis Society. "We must do more."

More than a dozen medicines for relapsing multiple sclerosis have been approved since the ’90s, but the first DMT for the primary progressive form of MS, Ocrevus, was not approved by the FDA until 2017.

"Our work with Ocrevus has provided an earlier treatment option with a favorable benefit-risk profile," says Hideki Garren, MD, PhD, global head of multiple sclerosis and neuroimmunology at Genentech, developers of Ocrevus. "This is because we know treatment with a high-efficacy medicine that impacts MS disability progression, not just relapses, is important to preserve patient function and ultimately quality of life."

Ocrevus is the first and only therapy approved for all relapsing forms of MS, which includes relapsing-remitting and active or relapsing, secondary-progressive MS as well as primary progressive MS.

"Ocrevus has fundamentally
It is now 2019 and every treatment that has gotten into late-stage development for lupus since belimumab has failed.

changed our understanding of MS pathology and how to treat the disease," Garren says. "By uncovering the role of B cells in MS (when it was previously thought to be primarily a T-cell driven disease) we have created a high-efficiency medicine that can be used earlier because of its favorable benefit-risk profile and the ability to slow the progression of disease."

Genentech set the price to allow people to have the easiest path to access, and today Ocrevus is widely covered both in the U.S. and abroad. The manufacturer has not increased the price since launch and is committed to fair, reasonable pricing over the life cycle of Ocrevus.

“We are committed to helping people access the medicines they are prescribed and offer comprehensive services for people prescribed Ocrevus to help minimize barriers to access and reimbursement,” Garren says.

Lupus

Until 2011 and the FDA approval of belimumab, there were no new treatments approved for lupus. This biologic treatment interferes with a specific protein that supports the activation and survival of B cells, which play a pivotal role in lupus pathology.

Taken together, the more than 30 treatments that have failed in clinical trials for lupus since the early 1990s represent well over $1 billion in lost research and development funding and have left lupus as one of the most underserved diseases.

“It is now 2019 and every treatment that has gotten into late-stage development for lupus since belimumab has failed,” says Joan T. Merrill, MD, chief advisor for clinical development at the Lupus Foundation of America, and Director of Clinical Projects. Arthritis & Clinical Immunology Program, Oklahoma Medical Research Foundation.

“The good news is that there is no slow-down in development for lupus, and new agents are coming into early phase trials each year.”

She explains that more and more has been learned about the pitfalls in the clinical trials for this complicated disease and improvements have been made in trial design, patient selection, and a better biologic understanding of the patient subsets that may or may not respond to a given targeted treatment.

“Many have been some recent successful phase 2 trials and we are waiting to see if any of these new agents break through at the end,” Merrill says. “Current treatments in development include agents that target proteins that lie at various points along the type I interferon pathway, agents that are similar (but not identical to belimumab), and agents that affect other regulators of the immune system.”

In 2019, belimumab was approved for children for the first time.

RA

Rheumatoid arthritis (RA) affects multiple joints, including in the hands and feet and can cause irreversible damage to these joints resulting in pain and loss of functionality.

Alla Rudinskaya, MD, section chief of rheumatology at Danbury Hospital and medical director of Western Connecticut Medical Group Rheumatology, says the main goals of treatment for RA and other autoimmune diseases are to improve symptoms (pain, functionality), and prevent joint damage from occurring.

In 1998, the first biologic agents (infliximab and etanercept) were approved for treatment of RA. Over the past 20 years, options for RA treatment have grown exponentially and there are now several classes of biologic agents available to treat RA.

“The use of biologics has greatly improved the treatment and prognosis of RA. Biologics are made by using biotechnology and work by interrupting or blocking immune system signals causing inflammation and joint destruction,” Rudinskaya says. “The availability of more medications is great news for people with RA because if they don’t respond to one treatment, they can try another one to effectively manage the disease. Also with these newer medications, there is a greater chance for the disease to go into remission.”

Most medications to treat RA are covered by commercial health insurance plans, Medicare, and state health insurance. For example, the first line of treatment for RA, methotrexate (which is a DMARD—disease-modifying antirheumatic drug), is a medication that has been around for decades. It’s an effective medication and is relatively inexpensive.

“However, the newer medications, like biologics, are usually quite expensive,” Rudinskaya says. “Most health insurance plans may cover different biologics but may have restrictions or prefer some medications over others. Patients who cannot get their medications through their insurance may sometimes be eligible for patient assistance programs.”

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years.
The Growing Problem of Pharmacy Deserts

By Fred Gebhart

Pharmacy deserts, areas with low access to prescription medications, are a challenge. There could be nearly 100 million Americans without good access to pharmacies, but pharmacists are not rushing to fill the gap.

A few independent pharmacists are expanding their existing community practices with telepharmacies, either independently or in cooperation with medical clinics or retailers such as grocery and hardware stores, Federally Qualified Health Centers, hospitals, and other provider groups. That leaves pharmacy deserts as a tremendous opportunity.

"There are a number of options, all of them lesser than community pharmacy," says Anthony Ciaccia, director of government and public affairs for the Ohio Pharmacists Association. Ohio is seeing a surge in pharmacy deserts as unprofitable rural pharmacies close.

The National Association of Chain Drug Stores notes that 92% of Americans live within five miles of a community pharmacy, but five miles can be an impassable barrier if transportation is difficult. Patients who could walk to a pharmacy now have to drive—if they can.

"A lot of people go to mail order because it’s the best option when your nearest pharmacy is now five, 10, 20 miles away," Ciaccia says. "Amazon, if they were to enter the prescription market, would likely convert a lot of people because they do convenience better."

Physicians, nurse practitioners, and other prescribers are already moving in.

"They don’t want to dispense, it isn’t their expertise or their business," says Adam Chesler, PharmD, director of regulatory affairs for wholesale giant Cardinal Health. "But prescribers are getting judged, and reimbursed, based on patient outcomes. If there is no pharmacy nearby, it only makes sense to fill their patients’ prescription needs."

The Underserved

Nearly 70% of Americans take at least one Rx drug, a number that is likely to increase as the U.S. population ages. And older patients are among the most likely to have pharmacy access problems.

Researchers at the University of the Sciences in Philadelphia found that 39% of Pennsylvania census tracts are pharmacy deserts for older adults enrolled in state pharmaceutical assistance programs. Nationwide, at least 2.4 million rural residents are currently without adequate pharmacy access. And that is just the rural residents who are easy to count.

"That number only counts people..."
Pharmacy desert neighborhoods have a thriving consumer business scene. Pharmacies can’t make a sufficient profit on Medicaid and Medicare to keep the doors open. Public policy needs to focus on pharmacy access, not just on pharmacy prices.

Dima M. Qato, PharmD, MPH, PhD

A “pharmacy desert” is any area with poor access to Rx medications. Pharmacy access lags because of lower income, insurance status, higher prices, poor transportation, long distances, or a combination of those factors.

Dima M. Qato, PharmD, MPH, PhD, assistant professor of pharmacy at the University of Illinois, Chicago, launched the term “pharmacy desert” in a 2014 article in Health Affairs. The authors built on the concept of “food deserts” used by the U.S. Department of Agriculture—a census tract in which a substantial number of residents have low access to a supermarket or a large grocery store. The agency defines low access as more than one mile from a supermarket or a large grocery store in an urban area and more than 10 miles in a rural setting.

When Dima and coauthors mapped pharmacy deserts in Chicago in 2012, they found 32% of Chicago census tracts, home to about one million people, were pharmacy deserts. Pharmacy deserts were concentrated in the city’s South and West sides in neighborhoods that were largely Black or Hispanic.

Cardinal Health used the USDA’s 10-mile measure to map rural pharmacy deserts for this article. They found 2,177 rural towns between 500 and 5,000 population without a pharmacy within 10 miles.

In 2018, health policy researchers at the University of the Sciences in Philadelphia used the same 10-mile measure to evaluate pharmacy access for older patients enrolled in a state pharmaceutical assistance program. They found 39% of Pennsylvania census tracts are pharmacy deserts.

Like urban pharmacy deserts, USP researchers found that rural pharmacy deserts have a lower density of both chain and independent pharmacies, fewer 24-hour pharmacies, and fewer pharmacies offering delivery services. But unlike urban pharmacy deserts, rural Pennsylvania pharmacy deserts are predominately female, married, and white, reflecting the overall make up the state’s rural population.

Pharmacy deserts can also affect medication pricing. A 2017 study in The Journal of Allergy and Clinical Immunology found that the highest prices for esomeprazole in greater Nashville, TN were in zip codes with the lowest median income. The highest prices for captopril were in areas where patients had to travel more than six miles to fill their scripts.
pharmacy deserts and more than 100 million Americans have problems getting to a pharmacy.

Qato coined the term “pharmacy desert” in 2014, building on the U.S. Department of Agriculture concept of food deserts—areas without adequate access to food markets. She stumbled into the realities of pharmacy access while working for two major pharmacy chains in Chicago.

As a fl oater, Qato quickly recognized that some neighborhoods had fewer pharmacies. If a prescribed drug was out of stock, she could easily transfer prescriptions to another store. But going to another pharmacy wasn’t always practical, even if it was only a mile or two away.

“There were neighborhoods where patients told me that just wouldn’t work,” she says. “They’d tell me they would have to take two more buses to get to that other pharmacy and more transfers to get home again. When I moved to academia, it was natural to look at why some neighborhoods had good pharmacy access and others didn’t.”

There are multiple factors driving disparities in pharmacy access, Qato says. Poor neighborhoods have fewer pharmacies than better off neighborhoods. Minority neighborhoods have fewer pharmacies than white neighborhoods with similar income levels. The key factor seems to be insurance coverage and the resulting pharmacy reimbursement.

“At least in Chicago, neighborhoods where residents have more Medicaid and Medicare coverage or are uninsured are much less likely to have adequate pharmacy access,” she says. “It’s a business problem specific to pharmacy. Those pharmacy desert neighborhoods have a thriving consumer business scene. Pharmacies can’t make a sufficient profit on Medicaid and Medicare to keep the doors open. Public policy needs to focus on pharmacy access, not just on pharmacy prices.”

Creating Pharmacy Deserts

Difficult access to healthcare services is not new in rural areas, (sparse rural populations don’t easily support healthcare providers any more than they support multiple retail businesses); however, pharmacy deserts are relatively new, spawned by recent pharmacy closures.

The Rural Policy Research Institute at the University of Iowa College of Public Health found that 1,231 independently owned rural pharmacies closed between 2002 and 2018, 16.1% of the total rural store count. The most dramatic decline occurred between 2007 and 2009, but closures continue.

Ohio lost 20 largely rural pharmacies in early 2019. The Ritzman chain, a regional staple for decades, sold to CVS, which closed 16 stores. Instant pharmacy deserts, Ciaccia says.

The problem is reimbursement, particularly Medicaid and, to a lesser extent, Medicare Part D reimbursement, he says. Ohio has increased Medicaid spending by 20% in recent years, but the additional dollars have largely disappeared at the PBM level and never reached beneficiaries or pharmacies.

“CVS Caremark is noteworthy because it has a very obviously competing retail arm that benefits every time a competing pharmacy closes,” Ciaccia says. “But I can’t name a PBM that doesn’t have its own mail order or specialty pharmacy that profits from reduced retail competition. Community pharmacy closures are a benefit to the companies that price them out of the market by cutting reimbursement.”

Ohio’s state Auditor found that PBMs had extracted $244 million from the Ohio managed care Medicaid program using spread pricing, Ciaccia notes. After the then-Auditor Steve Yost was elected Attorney General in 2018, the state sued OptumRx for overcharges to the workers compensation program. Yost calls the suit the first raindrops in a storm coming to PBMs in Ohio. Similar reimbursement problems help create and expand urban pharmacy deserts. Pharmacies
with a high proportion of patients on public insurance can’t afford to remain in business. And as independent owners move into retirement age, it is increasingly difficult to find buyers for low-profit stores.

At the same time, chains are closing less profitable outlets. Walgreens is closing 200 unprofitable U.S. pharmacies. CVS is closing 46 unprofitable stores and will close others as it reevaluates the 500 store leases that come up for renewal annually. Both chains are reducing new store openings.

“Good business moves for the chains,” Qato says, “and bad for patients and their health outcomes.”

**Filling the Gaps**

Pharmacy deserts don’t have to be forever. The latest J.D. Power survey of pharmacy customer satisfaction found that patients far and away prefer face-to-face pharmacy services to mail order or any other alternative. More thorough pharmacist discussions produce higher customer satisfaction and customers are happiest with independent pharmacies.

“Satisfaction is highest when you talk with a pharmacist or a technician in person versus over the phone or channels such as email, or chat,” says J.D. Power analyst Gregory Truex.

But those high satisfaction scores only apply to customers who can actually get to a pharmacy. That’s an invitation to expand into pharmacy deserts.

One possibility is new financial incentives for pharmacies in underserved areas. Federally Qualified Health Centers (FQHC) subsidize medical services, but most FQHCs are without a pharmacy. Qato recommends adding pharmacy services to the FQHC mandate.

The NCPA is pushing improved pharmacy access at both the state and federal levels. States from Oregon and California to Arkansas, Louisiana, and Virginia are requiring better pharmacy access, improved dispensing fees, stronger PBM oversight, and other patient- and pharmacist-positive changes in their Medicaid programs, says Ronna Hauser, NCPA vice president for policy and government affairs operations.

“Reimbursement is the main issue in pharmacy closures that contribute to pharmacy deserts,” Hauser says. “States are making it more obvious that they want to help pharmacies succeed and continue to stay open in these underserved areas.”

Telepharmacy is a faster fix. About half of states allow telepharmacy and more are moving toward implementation.

“We are seeing a major shift in states adapting regulations to work with telepharmacy,” says Jennifer Bingham, PharmD, clinical pharmacy specialist in Tucson and former chair of the APhA’s telehealth special interest group. “In the next five years or so you will see telehealth as an additional credential that we can offer.”

Norman Schlecht, PharmD, opened one of the nation’s first community-based telepharmacies in 2001 in Gwinner, ND, a town of about 500. He turned a pharmacy desert into a profitable pharmacy.

“They had a medical clinic, but no pharmacy,” Schlecht says. “Telepharmacy was a big improvement over having to drive 20 to 25 miles each way to get to a pharmacy.”

What began as a rural solution works just as well in urban pharmacy deserts. Tushar Mehta, RPh, opened the Broadway Medical Clinic Pharmacy in suburban Chicago in 2016. His telepharmacy is in a medical clinic in a blue-collar neighborhood with large Medicare/Medicaid populations and no brick-and-mortar pharmacy.

Mehta already owned two brick-and-mortar pharmacies a few miles away.

“Most of our telepharmacy patients are walk-ins, without working cars,” he says. “Too many times they never filled prescriptions because the nearest pharmacy was a mile or two away from the doctor. Patients got frustrated and never filled their scripts. Putting a pharmacy inside the clinic made those access issues go away.”

Low reimbursement from public insurance programs made a traditional pharmacy financially impossible, he adds. At 400 scripts per week, the telepharmacy turns a small profit.

“We have Medicare, Medicaid, a few private insurance patients. If I put everything together, I can afford to stay open because I don’t have a dedicated pharmacist salary. If this was a traditional pharmacy, it would be a money loser,” Mehta said.

Dale Colee, RPh, took a slightly different approach in Decatur, IL. He partnered with a FQHC to open Colee’s Community inside Crossing Healthcare. He also owns two brick-and-mortar pharmacies in Decatur.

“Reimbursement rates are low in public aid managed care programs in Illinois, like they are in every state,” Colee says. “The only economically feasible route was to open a telepharmacy. When patients walk in, they can see a physician or nurse practitioner and get their script filled without ever leaving the building. And because we are part of a 340B program, we get a dispensing fee on brand name products that actually covers our costs. And we don’t lose nearly as much on generics.”

“We can do okay on 125 to 150 scripts a day because our biggest expense, a $150,000 pharmacist, is gone. If we had to run The Crossing as a brick-and-mortar pharmacy like our other stores, we’d be in big time financial trouble.”
Antimicrobial Stewardship
Protecting Global Health

By Jennifer Gershman, PharmD, CPh

According to the Centers for Disease Control and Prevention (CDC), at least 2 million individuals are infected with antibiotic-resistant bacteria annually, resulting in more than 23,000 deaths. Antimicrobial stewardship programs offer strategies to improve appropriate antibiotic use, which can enhance patient outcomes and reduce adverse events. Pharmacists can play an important role through an interdisciplinary approach in the community and hospital settings.

Judicious Use
Antibiotics can be lifesaving, but they must be used judiciously to prevent antimicrobial resistance that can ultimately lead to longer hospital stays, higher medical costs, and increased mortality. The World Health Organization (WHO) considers antimicrobial resistance to be one of the 10 threats to global health in 2019. A variety of infections including pneumonia, tuberculosis, gonorrhea, and foodborne illness are becoming more difficult to treat. Overuse and misuse of antibiotics are the driving forces contributing to AMR, and it can also lead to serious adverse events such as Clostridioides difficile infections. One example is the widespread use of antibiotics for viral infections. According to a study published in the *Journal of the American Medical Association* (JAMA), at least 30% of antibiotics prescribed in the United States are unnecessary.1 Hospitals can also be affected by antimicrobial-resistant infections. In a study published in *Clinical Infectious Diseases*, 399 patients were assessed for multidrug-resistant organisms (MDRO) from two hospitals.2 The study found that 14% of patients had MDRO present on them at baseline. Also, 10% of patients had an MDRO contained on their hands.2 This emphasizes the importance of patient hand hygiene to reduce the transmission of infections.

Fighting Antibiotic Resistance
Fighting antimicrobial resistance in both the community and hospital settings is extremely important. Evidence demonstrates that antimicrobial stewardship programs improve patient outcomes, reduce antimicrobial resistance, and decrease healthcare costs. Pharmacists should educate patients and healthcare providers about antimicrobial resistance and appropriate use of antibiotics (See sidebar, pg. 34).

Check with patients to ensure they are up-to-date on all recommended immunizations, as vaccine preventable diseases could cause infections that lead to antibiotic use. Pharmacists can administer any needed vaccines, which can help to reduce antibiotic resistance.

U.S. Antibiotic Awareness Week is Nov. 18-24, which is an annual observance to raise awareness of antimicrobial resistance and the importance of appropriate antibiotic prescribing and use. The CDC has provided free educational materials for patients, pharmacists, and other healthcare professionals (available at: cdc.gov/antibiotic-use/community/index.html).

The WHO has just launched the AWARe tool (aware.essential meds.org/groups) with a goal to prevent antimicrobial resistance by classifying antibiotics into the following three groups: Access, Watch, and Reserve. The Access group indicates the first- and second-line options for each of the 25 most common infections that should be available at all times as well as affordable to the public. The WHO has a goal that by 2023, 60% of all antibiotics consumed should come from the Access group, since these medications have the lowest risk of antimicrobial resistance. For example, amoxicillin (Access group) is considered the drug of choice for strep throat. The Watch group includes first- and second-line antibiotics that should be used for a specific, limited number of infections. Finally, the Reserve group should only be used as a last resort for MDROs and be closely monitored. Colistin is often reserved for MDROs associated with pneumonia.

The Infectious Diseases Society of America has published evidence-based practice guidelines for evaluating antimicrobial stewardship programs and emphasizes the importance of physician and pharmacist leadership as well as infectious disease expertise. The need for antimicrobial stewardship programs has been recognized in the National Action Plan for Combating Antibiotic-Resistant Bacteria by the White House in March 2015, which calls for establishing antimicrobial stewardship programs in all acute care hospitals by 2020.

The structure of these programs is addressed in the CDC’s Core Elements of Hospital Antibiotic Stewardship Programs (See Table, pg. 36).3 Unfortunately, about a quarter to a half of all antibiotics prescribed in U.S. acute care hospitals are believed to be unnecessary or inappropriate.3

CONTINUED ON PAGE 34>
SPECIAL REPORT

Patient Outcomes
Automatic changes from intravenous (IV) to oral antibiotic therapy when appropriate can improve patient safety. Fluoroquinolones, trimethoprim-sulfamethoxazole, and linezolid are some examples of antibiotics with good oral absorption. Renal dose adjustments for antibiotics are also important in patients with renal dysfunction. Other pharmacy interventions may include dose optimization, assessment for duplication of therapy, automatic stop orders, and prevention of antibiotic-related drug-drug interactions.

Antibiotic "time outs" are important since antibiotics are often initiated empirically while cultures are being obtained. After 48 hours, the treatment should be reviewed to determine if the antibiotic selected was appropriate and whether the dosage and duration of therapy are correct.

Information technology staff can facilitate antimicrobial stewardship programs by incorporating drug information guidelines at the point of care, implementing clinical decision support tools for antibiotic use, and creating prompts for clinicians to review antibiotics. It is also critical to monitor antibiotic prescribing and report clinical interventions and outcomes to improve antibiotic use. Providing education that includes antibiotic drug information, patterns of antimicrobial resistance, and case studies can also play an integral role in the success of antimicrobial stewardship programs.

Resources for Pharmacists
Timothy Gauthier, PharmD, BCPS-AQ ID, is an antimicrobial stewardship and infectious diseases pharmacist practicing in Miami, FL, who created the ID-stewardship website (idstewardship.com), which provides pharmacists and other healthcare professionals with up-to-date information about antimicrobial resistance and antimicrobial stewardship programs. The content is written by experts in the area and is divided into three main free open-access sections. The resource center is geared toward those interested in antimicrobial stewardship programs and provides links to open-access institutional antimicrobial stewardship program websites, clinical practice resources, important guidelines, educational opportunities, learning activities for children, and much more.

Antibiotic Counseling
Pearls for the Community Setting

- Antibiotics should never be taken for viral infections
- Never save antibiotics to use when sick in the future
- Never take an antibiotic prescribed for someone else
- Always complete the full antibiotic treatment course
- Never take expired antibiotics
- Safely dispose of unused and expired antibiotics through a drug disposal program or in the household trash
- Household trash disposal instructions:
  1. Remove the antibiotic from the original container and mix with coffee grounds, dirt, or cat litter
  2. Place the mixture in a container or storage bag
  3. Throw the container in the garbage
  4. Remove all personal information

“As someone obsessed with the topic, I frequently update this page with the latest and greatest stewardship resources (many of which these days are found via social media),” says Gauthier. The website includes articles written by experts about a variety of hot topics including residency and training, pharmacy news, and practical advice for pharmacists and students. The basic study guide is another resource with important talking points on various antimicrobial agents along with drug photos and links to relevant articles. There is also a section called IDstewardship Training at LearnAntibiotics.com.

Gauthier’s development of this digital resource was based on a perceived need in the pharmacy community. “It all started with Instagram, which I started using professionally in early 2014 after watching a show on PBS’s Frontline called “Generation Like.” This episode showed me that social media is the future, and I thought if we can combine this with pharmacy education and scholarship.

Gauthier is passionate about IDstewardship and enjoys providing antibiotic expert information through writing in his free time as a creative outlet.

Gauthier provides insight into the global spread of antimicrobial resistance and the importance of reducing unnecessary antimicrobial use whenever possible by getting the right diagnosis, right drug, right dose, and right duration of treatment for infections. Antibiotics should not be prescribed when they are not needed, and when they are indicated, it is crucial to use them wisely. Pharmacists can play an important role in antimicrobial stewardship programs, and Gauthier contributed to the Society of Infectious Diseases Pharmacists outpatient care position statement on the topic.

“Pharmacists can promote awareness...”
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of the current antimicrobial resistance problems and encourage safe antimicrobial drug use. As a trusted member of society, pharmacists are well positioned to help (especially in this time where misinformation is so prolific on social media),” says Gauthier. “Pharmacists can also use their pharmacotherapy and healthcare systems expertise to improve care. This can be through developing resources, improving elements of practice, or making patient-specific interventions.”

Gauthier also discussed the future of antimicrobial stewardship and how the programs will continue to develop and expand as organizations such as The Joint Commission are making this a priority to fight antimicrobial resistance.

“I believe pharmacists in all practice settings will play an increasingly important role in formalized antimicrobial stewardship program activities, and I hope IDstewardship can continue to be a valuable resource as this occurs,” says Gauthier.

Lily Garcia, PharmD, BCPS, is an infectious diseases clinical pharmacist specialist at Broward Health Medical Center (BHMC), in Ft. Lauderdale, FL. Garcia described that the antimicrobial stewardship program at BHMC aims to meet all of the seven core elements recommended by the CDC and includes pharmacists and physicians leading the program. Pharmacists provide their drug expertise to prescribers and perform daily interventions such as IV to oral dose conversions, renal dose adjustments, and vancomycin/aminoglycoside monitoring. “As an infectious diseases clinical specialist, I have an active role in new policy development and implementation as well as tracking and reporting of antimicrobial prescribing practices. I monitor hospital-wide antimicrobial use to ensure appropriate utilization of high cost/restricted antimicrobials and serve as a resource to my colleagues and physicians for appropriate prescribing and monitoring,” says Garcia.

Garcia is involved in training students and residents on clinical rotations. “The overuse and misuse of antimicrobials secondary to a lack of practitioner education and unlimited access to broad spectrum antibiotics are the greatest factors contributing to antimicrobial resistance.”

The decentralized pharmacist model at BHMC enables pharmacists to actively educate prescribers in real time about appropriate antimicrobial use. Garcia helped to develop hospital acquired infections (HAI) performance improvement committees that review patients with HAIs and provide guidance on how to manage these cases. Hospital staff are also provided with education through newsletters that include important information regarding antibiotic resistance, policy updates, and restricted antimicrobials.

### TABLE Key Elements to Hospital Antimicrobial Stewardship Programs

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**LINKS**

**IDstewardship:** idstewardship.com

**IDstewardship training:** training.idstewardship.com/training-headquarters

**REFERENCES**


Community pharmacy’s future hinges on changing the pharmacy payment model. It’s necessary for your continued business success. Attend NCPA 2019 Annual Convention to discover innovative, peer-tested solutions designed to invigorate your practice like:

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Visit convention.ncpanet.org/program for a complete list of business education programs to help you thrive – rather than just survive – in community pharmacy.
By Fred Gebhart

The Unintended Consequences of Clinical Pharmacy Services

Everything a pharmacist does has consequences. Especially moving toward increased clinical services. As the pharmacist moves closer to the top of their scope of practice, the entire pharmacy support staff must amp up their own practice. Technicians, clerks, even front-end cashiers take on new responsibilities to support the pharmacist’s increasing clinical role.

Technicians aren’t just running dispensing robots; they are managing the entire dispensing process. In some states, techs are checking other technology, administering vaccines, running telepharmacies, and filling in other duties once considered the pharmacist’s responsibility.

Clers are moving up to fill dispensing-related tasks once reserved for techs, often becoming techs themselves. Cashiers aren’t just running registers, they are becoming living, breathing, smiling information resources who direct patients to the latest product and service offerings throughout the pharmacy.

Increasing support staff involvement in the provision of clinical pharmacy care does more than shift repetitive pieces of dispensing, inventory management, medication history, and other mechanical tasks away from pharmacists.

“It is a paradigm shift in the use of technicians or other pharmacist extenders,” says Eric M. Maroyka, PharmD, BCPS, director of the Center on Pharmacy Practice Advancement for the ASHP. “Most states have recognized pharmacy technicians and have changed scope of practice to empower technicians to take medication histories and perform other tasks that used to require pharmacists. Staff can be repurposed to perform higher level tasks that can close quality and safety gaps. That frees up the pharmacist to pivot to a more service-based model working with the interprofessional care team or as an independent practitioner.”

Carlie Traylor, PharmD, associate director of strategic initiatives for the NCPA, has worked with the new paradigm firsthand. She moved to NCPA after serving as Clinical Director of Chancy Drugs, a group of independent pharmacies in Georgia.
“A generation ago, the pharmacist’s role was to input the prescription,” Traylor says. “Now it has evolved into a technician role. We are seeing this happening in the clinical field as well—medication therapy management, immunization, patient education, medication adherence, medication synchronization. Technicians can be your foot soldiers to effectively triage patients and facilitate pharmacists to have more effective and efficient clinical interactions with more patients.”

Empowering support staff can be a major boost for pharmacists working in comprehensive medication management in almost any setting. Jill Borchert, PharmD, professor and vice chair of pharmacy practice at Midwestern University Chicago College of Pharmacy was lead author on a 2018 American College of Clinical Pharmacy white paper on incorporating pharmacy techs and other support personnel into patient care processes.

Best practices focus on matching the right support staff with the right task to help the pharmacist focus on the tasks that best match their training.

Borchert works in ambulatory care, rooming patients, preforming point-of-care testing, documenting care. Does it really take a PharmD to test for strep infection? Or take a medication history? “Much of what we do may not require advanced training,” she says. “There’s good evidence that trained technicians can be truly effective in collecting patient information, performing some of those initial portions of medication reconciliation, documenting care, supporting the pharmacist. If we could be more efficient using support staff, we could potentially expand the reach of the pharmacist, see more patients, even potentially lower the overall cost of care.”

Travis Wolff, PharmD, BCACP, thinks of support staff in terms of return on time investment (ROTI). Wolff, and his wife, Sunni Wolff, PharmD, own Med-World Pharmacy in Sapulpa, OK and Apothecary Pharmacy in nearby Mounds.

They also run PharmFurther, a coaching business that helps community pharmacists work smarter instead of harder. “Working smarter,” according to the Wolffs, includes delegating every possible task to support staff. Running a pharmacy efficiently and effectively means managing resources efficiently and effectively. A pharmacist’s most valuable, most limited resource is time.

“We’ve learned the hard way to ask every time if this is a clinically relevant task that requires a pharmacist’s clinical decision-making or to meet a regulatory requirement. If it doesn’t come down to one of those two things, you probably shouldn’t be doing it yourself,” says Wolff.

“We delegate and filter that ROTI concept through everyone’s workflow and systems. If you don’t delegate tasks that your support staff should be doing, you become the bottleneck in the pharmacy workflow and patient care. The rest of the staff can’t do their jobs properly because you are getting in the way and slowing them down.”

**Evolution Across Settings**

What to call those non-pharmacist staffers is unclear because staff roles, like pharmacist roles, are governed by state law.

A task that might require a tech in one state might be done by a clerk in another state and not specified in another jurisdiction. Where some states require little more than a registration for techs, a growing number of states require accredited training and third-party certification to work as a tech.

“IT ends up being that collective group of pharmacy personnel, namely pharmacy technicians, that are a great group to step into these changing roles,” notes David R. Bright, PharmD, associate professor of pharmaceutical sciences at Ferris State University College of Pharmacy.

“We may end up seeing more of a differentiation between more advanced technicians and entry level technicians. The Pharmacy Technician Certification Board is creating an advanced technician designation and credentialing to support the profession moving in that direction.”

Bright likens the growing importance of pharmacy technicians to similar changes in medical practice.

Medical practices have evolved from a physician-nurse-receptionist to include the physician, physician’s assistants, nurse practitioners, medical assistants, billing clerks, insurance and patient assistance program specialists, and more. Just as the physician remains responsible for the entire practice and depends on a growing variety of mid-level practitioners and support staff, pharmacy is developing its own cadre of support staff.

The composition of the pharmacy...
team, and the tasks each member performs, depends on state law, the needs of the practice and its patients, and the pharmacists’ own preferences.

“We have pharmacies with four or five pharmacists and the demands on the technicians are very different than in stores with a single pharmacist,” says Brian Hille, BSPharm, vice president of specialty and wellness services for Albertsons Companies.

“The direction of travel has been to allow greater technician assistance to the pharmacist. Every pharmacy operates a little differently and you have needs and demands according to the type of pharmacy, the patient population, the volume, the needs of the pharmacist. In our Idaho stores, technicians are administering vaccinations. Just as vaccinations opened the door for a lot of clinical services by pharmacists, doors are opening for technicians.”

A Professional Career Ladder

It wasn’t long ago that techs did little more than fill pill vials. In 2019, techs are taking on a growing variety of duties in pharmacy administration and management, quality control and assurance, sterile and nonsterile compounding, and a growing list of patient-facing clinical tasks, starting with point of care testing and immunizations.

“It’s still early, we’ve only seen two states go down that immunization path,” says Bill Schimmel, PTCB executive director and chief executive officer. “And we are seeing this same conversation at other boards of pharmacy. These conversations around hiring, training, and delegation by pharmacists are happening in every board of pharmacy as well as state and national pharmacy associations. And almost every employer out there is having the same discussion, from large chains to independent pharmacies.”

Maroyka likened the shift to radiology. Radiology techs once did little more than adjust radiation shields and position film sheets for x-rays. The radiologist did everything else. Today, radiology techs do everything except read and interpret the image.

“[Radiology technicians] have created a very structured set of credentials and have carved a path to a recognized career,” Mayorka says. “That is what we are doing as we look to professionalize the pharmacy technician workforce.”

ASHP and the Accreditation Council for Pharmacy Education revised accreditation standards for tech education and training following a consensus conference in 2017. Effective at the start of 2019, nine standards were added to the previous six, and emulate the elements of pharmacist training and education programs while emphasizing collaboration with pharmacists and other members of the healthcare team.

PTCB built on those new standards to roll out its own Advanced Certified Pharmacy Technician (CPhT-Adv) credential. The new credential is supported by new assessment-based certificate programs that will launch in late 2019 and 2020.

The first five programs include Technician Product Verification (TPV), Medication History, Controlled Substance Diversion Prevention, Billing and Reimbursement, and Hazardous Drug Management.

To earn the CPhT-Adv certification, CPhT level techs need three years of work experience plus four of the first five assessment-based certificates.

No One Left Behind

The new accreditation standards and certificates continue to recognize the value of on-the-job training, says Lisa Lifshin, BSPharm, ASHP’s director of Pharmacy Technician Program Accreditation & Residency Services. The ultimate goal is for all pharmacy technicians to complete a formalized, standardized training program.

“Similar to pharmacists who have gone through pharmacy school, we want every prospective employer, every state board of pharmacy, to know what each level of technician has been through and can be expected to know,” Lifshin says. “That is the point at which we can all go back and say let’s have another look at technician ratios to help pharmacists meet their full potential in patient care.”

Standardizing support staff training and certification is no easier than standardizing anything else in pharmacy across 50 state practice acts and pharmacy boards. The process starts with one or two states willing to trial an innovative practice such as allowing pharmacists to prescribe specific medications or allowing technicians to administer vaccination.

“The question is making those a practice standard nationally,” says Elizabeth Cardello, RPh, senior director of corporate alliances for the APhA. “[APhA] is working collaboratively with other pharmacy associations, the practice community, and regulatory entities to make sure best practices become standard and consistent. We did it with immunization protocols across all 50 states and we will do it in these other areas as well.”

The next changes to standard practice could be in TPV, which allows technicians to take on a larger portion of the dispensing process, Schimmel predicts. Expect to see more technicians taking charge of inventory management, purchasing, scheduling, billing and reimbursement, serving on pharmacy boards, and taking patient information.

One thing techs are unlikely to be doing anytime soon is counseling patients.

“Pharmacists have extensive training, knowledge, and expertise,” Schimmel says. “If I have a question about my prescription, I really do want to talk with the pharmacist.”
Cups of Profits

Pharmacies turn to unique offerings to increase revenue

By Keith Loria

Pharmacies were once known for their soda fountains, with customers enjoying a cherry coke or root beer while they waited, catching up with neighbors, reading the paper or just taking a breather from their day.

While you don’t see them that much today, there are still some pharmacies that add a coffee shop or small restaurant to their business model, evoking memories of that simpler time gone by. Not only do food and drink offerings please people, they often give them reason to come back and become regular customers of the pharmacy.

Wall Drug Store in Wall, SD, started as a simple pharmacy in 1931, but transformed into a major tourist attraction thanks to the forward thinking of original owners Ted and Dorothy Hustead. The drug store started offering free water and 5 cent coffee to travelers on their way to Mount Rushmore, and soon the store added a souvenir shop and restaurant. Over time, the store expanded to more than 76,000 square feet and added other attractions such as an art gallery, mall, and kid’s park.

Today, under the ownership of their grandson Rick Hustead, more than two million visitors come into town to see the historic pharmacy, grab a bite to eat and a cup of coffee—still for just a nickel.

It’s a business model that has been replicated by many pharmacies over the years.

A Tasty Treat

Tim’s Pharmacy in Yelm, WA, celebrated its 100th anniversary this summer. For most of that century, it’s offered some sort of refreshments. The latest offering is a combination coffee shop and ice cream parlor called Holy Grounds, which opened in March of 2011.

The pharmacy is now owned by the Quinby family, who purchased the operation last November. One of the main draws of the business was the Holy Grounds parlor.

“Many customers enjoy the nostalgia. They remember a time when their local pharmacy had a soda fountain and ice cream, and that helps to bring people in,” says Will Quinby, pharmacist and co-owner of Tim’s Pharmacy. “For some of our younger customers, they enjoy the idea of a classic pharmacy with a soda-fountain. We also make a point to serve high-quality coffee and ice-cream at a good price.”

The Quinby family sees the coffee shop as a “service asset,” and look for opportunities to serve their customers in unique ways that the other pharmacies are unable to match. For instance, it offers made-to-order lattes and coffee, ice cream, milkshakes, and a limited number of food items such as pre-made sandwiches, pretzels, and cookies.

“We have many customers who enjoy the uniqueness of Holy Grounds,” Quinby says. “We offer higher-end coffee and ice cream, so our customers know they are receiving high-quality at a good value.”

One of the secrets to success, he shares, is that it’s imperative to have employees who understand their role in the coffee shop.

“They must be friendly and approachable. It is very useful to have coffee employees with outgoing personalities that can help recognize service opportunities,” Quinby says. “It is also beneficial to find ways to keep those coffee employees busy throughout the day doing other tasks, but visibly ‘available’ to serve customers in the coffee shop.”

Even though people sometimes come in for the ice cream and coffee, Tim’s Pharmacy is a pharmacy first, and that’s the business’ mantra.

“In everything that we do, it is important for the staff to understand that the purpose of the coffee shop is to drive business to the pharmacy and serve those customers first and foremost,” Quinby says. “The coffee service
is a perk; having employees that understand and appreciate its role within the pharmacy can be a challenge."

Another challenge, according to Quinby, is some of the regulatory aspects of operating a food service, which are unique and outside the typical realm of a pharmacist.

When My Pharmacy opened in Hillview, KY, in 2016, owner and pharmacy manager Rebecca Hernandez chose to offer coffee and tea to her customers while they waited for their prescriptions to be filled.

"It doesn’t require too much space and we already lease the entire store, so I wanted to put the space to use the best that I could and make money," Hernandez says. "There’s a large family practice a few doors down from us, so a lot of customers come in here to wait and grab a cup of coffee."

The pharmacy has a full menu of offerings, including Bora organic coffee, espresso, hot chocolate, iced coffee, lattes, and more.

"Everyone who works here—my technicians and myself—chips in to help serve, so I didn’t need to hire anyone else," Hernandez says. "Everyone really loves it and I think it definitely keeps us on the mind of people when they need a pharmacy to go to."

**New to the Game**

Ann Deaton Redding opened Crossroads Pharmacy in Smiths Station, AL, in March of 2018, bringing a brand-new type of pharmacy to the area.

"I've practiced for 29 years and I've always been a chain pharmacist, but I was tired of treating people like a number, and I wanted to see people as they are," she says. "My husband and I decided I needed to start my own pharmacy and while we were coming up with a business plan, we decided to offer some type of food element in front to help bring people through the doors."

Originally, Redding considered having some sort of restaurant, but that seemed to require a little too much involvement, so she reduced the idea down to a coffee bar. In her mind, the coffee bar to people in 2019 is akin to the soda fountains of 50 and 60 years ago and helps her overall business.

"We pretty much have a mini-Starbucks in here, and we make almost anything they, or any of the other big guys, can make," she says. "We took our staff to barista school to be trained, so they know how to work all the machines properly because we didn’t want to have a staff of people who didn’t know what they were doing. We wanted to be as good as the major coffee players in the game."

It helps that in the town of Smiths Station, there’s not any really good specialty coffee shops, and the closest ones are at least 20-30 minutes away.

"We thought it was time to bring a high-end atmosphere to where we are and the coffee bar has really added into that," Redding says. "The way pharmacy is now, compared to how it was 10 years ago, you need to find something else. A new spin to be profitable. An independent pharmacy isn’t going to survive today just from prescriptions."

The biggest challenge with achieving success has been to change people’s mindset about pharmacy and the corporate mentality.

"People pretty much channel to big chains like Walmart or Walgreens because they have big money and can hound people with repetitive ads, which draws people in," Redding says. "We need to get people thinking more about the community pharmacy and the benefits it offers. We try to greet everyone and have one-on-one personal interactions."

Crossroads Pharmacy relies on word of mouth and social media to get the word out about its great coffee and even better service. Redding has also done some local radio and TV spots to up the marketing a bit.

"When we first started, it took a while for business to get ramped up, but today, probably 40 to 50% of our pharmacy customers get something, whether it’s a smoothie, a frappe, coffee, or some pastries that we bring in from a local bakery," Redding says. "The key is, it’s all about the experience. I wanted to provide a relaxing atmosphere where people could walk in and not feel like they were in the rat race—even if it was just for 15 minutes."
Recent pharmacy staff layoffs at Walmart and Sam’s Club—along with Walgreens and CVS closing some stores—are shining a spotlight on the ever-increasing pharmacy jobs problem.

In community settings in particular, there are simply not enough open positions for all of the pharmacy graduates as well as those changing jobs due to layoffs and other reasons.

Some pharmacy experts and veterans blame DIR fees and other expenses that are harming pharmacies’ bottom line, while others say there are just too many retail pharmacies and not enough pharmacists qualified to work in specialty areas such as oncology and endocrinology.

“Pharmacy as a whole is challenged by PBM tactics that interfere with pharmacists’ ability to treat patients and make it more difficult for pharmacies to stay afloat. In addition to expanding pharmacists’ scope of practice, reining in PBMs’ tactics would assist pharmacy’s decision-making about staffing abilities and whether to expand or even maintain a pharmacy business,” says Andrea Pivarunas, director of public affairs for the National Community Pharmacy Association (NCPA).

“Various players have been taking money out of the drug distribution system for many years, but it has been much worse in past two to three years largely, I believe, due to DIR fees,” says Lucinda Maine, RPh, executive vice president and CEO of the American Association of Colleges of Pharmacy (AACP).

In addition, the competitive landscape has changed over the last 25 years, according to Maine. “It’s possible that there wasn’t enough business to put a pharmacy on every corner [in certain cities]. And then you add in mail order... and online retailers have dented [brick-and-mortar] business,” she says.

Pharmacy closures and staff layoffs can also be attributed to viewing pharmacists as only drug dispensers. “We haven’t yet developed the consistent patterns of compensation for pharmacist services—the value-added services that pharmacists can and should be providing the public,” Maine says.

Plus, the demand for pharmacist and tech jobs, and the required pharmacy schools to train them, has boomeranged the shortage of pharmacists in 2000. The pace of new school openings between 2001 and 2018 was “dizzying,” including the establishment of multiple satellite sites and branch campuses, Maine wrote in a commentary in the American Journal of Pharmacy Education.

The number of pharmacy schools and colleges soared from 83 in 2002 to 142 in 2018. The number of graduates in spring 2018 numbered slightly more than 14,500. In addition, more than 325,000 pharmacists were licensed in the United States in 2017, according to the National Association of Boards of Pharmacy (NABP).

Some pharmacy school graduates were so upset about their job prospects after graduation that they urged the public to sign a petition, “Halt New PharmD Accreditation to 2030.” It was signed by...
almost 10,000 additional petitioners in just a week, Maine says.

"The fundamental premise is that the job market for pharmacists can no longer accommodate the number of PharmD graduates. They specifically asked the American Association of Colleges of Pharmacy, the Accreditation Council for Pharmacy Education, and the American Pharmacists Association to take action to prevent the opening of more new schools," Maine writes in the commentary.

The petitioners' request is not legally defensible, Maine says. Instead, pharmacists need to be reimbursed for the services they provide. More pharmacists are being reimbursed via insurers that recognize how pharmacists prevent future health problems and thereby save the plans a significant amount of money.

Physicians want specialists, such as clinical pharmacists who specialize in endocrinology.

**Solutions to the Jobs Crisis**

"NCPA strongly advocates for greater pharmacist involvement in health care, along with appropriate levels of compensation. Not only does this improve health outcomes and help address patients’ potentially unmet health needs, it also can lead to additional opportunities for pharmacists and pharmacy students,” Pivarunas says.

The need for pharmacists and additional health care providers will only grow as the American population continues skewing older—and, consequently, more ill—particularly in communities that are already underserved, Pivarunas adds.

There is an increasing amount of revenue from services such as vaccinations and medication management that community pharmacies could appropriately take advantage of—when staffed appropriately, according to Maine. “There is payment available for [some services, but it is not being services that partner with health plan sponsors seeking to better manage their overall healthcare costs.

"More than 2,000 pharmacies have come together to participate in these local networks, and the number is growing as more and more pharmacies look to be rewarded for providing cost savings and quality value beyond dispensing," Pivarunas says.

Meanwhile, NCPA and the NCPA Foundation have established the annual Good Neighbor Pharmacy NCPA Pruitt-Schutte Student Business Plan Competition to help prepare tomorrow’s pharmacy entrepreneurs for a successful future. "The goal of this competition is to motivate student pharmacists to create the blueprint necessary for buying an existing independent community pharmacy or developing a new pharmacy,” Pivarunas says.

Webinars and workshops, such as NCPA Innovation Center’s Ownership Workshop, can also facilitate networking opportunities and outline pathways to pharmacy ownership and management. "NCPA’s advocacy efforts and business education programs are aimed at growing the number of independent pharmacies, helping to create more jobs for future pharmacists,” Pivarunas says.

NCPA’s advocacy efforts and business education programs are aimed at growing the number of independent pharmacies, helping to create more jobs for future pharmacists.

MORE THAN 325,000 PHARMACISTS were licensed in the U.S. in 2017

DrugTopics.com | September 2019 | DrugTopics 43
**NEW DRUG REVIEW**

**Pretomanid:** for Highly Drug Resistant Tuberculosis

Pretomanid is a nitroimidazole antimicrobial for the treatment of extensively drug resistant (XDR-TB) and treatment-intolerant or non-responsive multidrug-resistant pulmonary tuberculosis (MDR-TB). It is indicated as part of a three-drug oral combination with bedaquiline and linezolid, or the BPaL regimen. BPaL offers novel treatment for a patient population with poor prognosis and limited treatment options.

**EFFICACY**

Pretomanid has been studied alone and in combination in 19 clinical trials with 1,168 total trial participants. Pretomanid has been evaluated in a pivotal phase 3 open-label trial, Nix-TB, as part of the BPaL regimen. Nix-TB enrolled 109 patients with XDR-TB as well as treatment-intolerant or non-responsive MDR-TB from three sites in South Africa. Patients were treated with bedaquiline 400 mg once daily for 2 weeks then 200 mg 3 times per week, plus pretomanid 200 mg once daily and linezolid 1,200 mg once daily for 6 months. The primary outcome measure looked at incidence of bacteriologic failure, relapse, or clinical failure through follow-up until 6 months after treatment completion. Pretomanid demonstrated favorable outcomes of relapse-free cure status in 95 of the first 107 patients 6 months after end of treatment.1, 2

**SAFETY**

The Nix-TB study also assessed the safety of pretomanid in combination with bedaquiline and linezolid. Of the 109 patients treated in this study, there were 8 deaths. Six patients died while receiving treatment and two died during follow-up. The most common adverse reactions reported in >5% of patients included peripheral neuropathy, acne, anemia, nausea, vomiting, musculoskeletal pain, and headache. Twenty-eight percent of study participants experienced increased transaminases; however, all patients in this group were able to continue therapy and complete the full treatment course. Peripheral neuropathy, a known side effect of linezolid, occurred in 81% of study patients but did not lead to discontinuation of the entire study regimen. Linezolid is likely responsible for most adverse events and all dose modifications.1, 2

ZeNix, the most recent clinical trial involving BPaL, aims to determine whether the efficacy of BPaL can be maintained while reducing toxicity with a lower dose and shorter duration of linezolid. ZeNix is a phase 3, multi-center, partially-blinded, randomized clinical trial with four parallel treatment groups. Linezolid treatment dose and duration will be double blinded. Results from this study will be released on a rolling basis.3

**DOISING**

Pretomanid is dosed 200 mg orally once daily in combination with bedaquiline and linezolid for 26 weeks total. Combination dosing includes bedaquiline 400 mg orally once daily for two weeks followed by 200 mg 3 times per week for 24 weeks, plus linezolid 1,200 mg orally once daily for 26 weeks. BPaL is administered by directly observed therapy. Dose adjustment recommendations for renal and hepatic impairment are not included in the manufacturer’s labeling, as they have not been studied in these limited and specific patient populations.4

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**REFERENCES**


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Megan E. Wein, PharmD, is a PGY-1 pharmacy resident at UConn Health Center in Farmington, CT.

Kevin W. Chamberlin, PharmD, is an associate professor and assistant department head of pharmacy practice at UConn School of Pharmacy in Storrs, CT.
Top Challenges in Managing Diabetes

By Ken Krizner

Individuals diagnosed with diabetes have to concern themselves about a variety of issues, like blood sugar level, diet, and a complex medication regiment.

“A lot is required of a person diagnosed with diabetes in terms of what to do and not to do,” says Amy Carter, MA, RD, CDE, director of Outpatient Nutrition for Eskenazi Health in Indianapolis. “Knowing they will have to manage this chronic disease for the rest of their lives, often without education, support, or financial resources, significantly impacts a person’s self-care ability.”

While there are lifelong challenges, the good news is diabetes is manageable, Carter says. Patients can control their condition by making the right choices.

Here are some of the leading challenges that endocrinologists and educators see from their daily interactions with diabetes patients.

Cost

“We have so many great medications available in our arsenal to treat diabetes,” says Patricia Luceri, DO, an endocrinologist with Jefferson Health in Marlton, New Jersey. “Unfortunately, they’re expensive. If the patient doesn’t have good insurance to cover the cost of the drug, then that drug is not an option. Even with insurance, there are copays, which could be high.

“Often, patients tell me they’ve had to choose between buying food or medication,” she adds. “Many times, they’re trying to stretch their medications by taking them every other day or taking a partial dose.”

Education

“The actual percentage of people who receive the appropriate education about how to manage their diabetes is fractional—less than 10%,” Carter says. “Full diabetes education encompasses food, medicines, checking blood sugar, risk reduction, and other topics. Without education, it’s very challenging for people to understand what happens if they don’t take the appropriate steps.”

Self-monitoring

“Patients often don’t have access to the supplies they need to monitor their blood glucose levels,” says Ajaz Banka, MD, an endocrinologist with Beaumont Hospital in Michigan. “Testing supplies are expensive. But if patients don’t know their numbers, they don’t know what’s happening [to their health].”

“If patients don’t test their sugar, they can’t manage their diabetes,” Luceri says. “It can be cumbersome to test regularly and test in public. There have been many advances in recent years, so this is becoming less of a challenge. There are continuous glucose monitors available to monitor their sugar in real time without a finger stick. However, not every insurance company covers the monitors.”

Medication Adherence

“Diabetics are always on multiple medications, not just for their diabetes but also for high blood pressure and high cholesterol,” Luceri says. “It can be tough to remember when you’re taking that many medications, often at different times of the day. There is a class of medications that have a once-weekly injection, which can help with compliance. Some companies have programs that will send reminders to the patient to take their medications.”

Healthy Lifestyle

“Eating is a basic function and asking a patient not to eat a particular food is difficult,” Banka says. “Patients are asymptomatic. They don’t really care, because they don’t see the complications right away, though they could still happen in the future. Cultural and educational background plays a big role in diabetes management. If we can get across to patients with education why managing diabetes is important, it will play a big role, long term, in their health.”

“It’s a difficult, long-term concern for people to incorporate diabetes management into their daily lives without feeling like it’s taking over,” Luceri says. “I discuss diet, exercise, and maintaining healthy eating habits with patients. But when they leave my office, it’s up to them to follow that advice.”
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