October is a special month for those in the pharmacy profession. As we head deeper into autumn, it’s time to recognize the important work of pharmacists across the country with American Pharmacists Month.

According to the American Pharmacists Association, this celebration of pharmacists began in October 1925. “For one week, radio stations across the country broadcasted special programming to highlight the profession of pharmacy,” their website reads. In 2004, what began as National Pharmacy Week became American Pharmacists Month and has remained a monthly celebration for the past 18 years.

Throughout the month, there are additional celebrations and observance days to celebrate and acknowledge all who are a part of the pharmacy profession:

**Women Pharmacist Day** will be observed on October 12, 2022. The 12th of the month was chosen to honor Elizabeth Gooking Greenleaf, widely known as the first female pharmacist in the United States. Greenleaf practiced pharmacy during the early 1700s as the first female apothecary in the 13 Colonies, and was also the mother of 12 children.

**National Pharmacy Week**, observed October 16 to 22, 2022, gives pharmacists the opportunity to celebrate their important role as health care providers, as well as raise awareness among patients about the vital services they provide.

**National Pharmacy Technician Day** will be observed during National Pharmacy Week on October 18. This is a day to recognize the important and invaluable contributions that pharmacy technicians provide to their pharmacy, their patients, and their communities.

Be sure to visit the Drug Topics® website throughout October for all of our American Pharmacists Month coverage.

Reference:

Thank you for reading,

Mike Hennessy Jr
President and CEO
of MJH Life Sciences®
Congratulations to the
2022 Winners!

The Best of the Best Pharmacy Awards, sponsored by SingleCare, honor exceptional pharmacists, pharmacy technicians, and pharmacy teams in communities throughout the U.S. In a time when they are often overworked and under-appreciated, pharmacy staff should be recognized and celebrated. These 25 winners represent the best of the best—they go above and beyond each and every day.

Read more about the awards and the winners’ stories at pharmacyawards.com
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Congratulations to the 2022 Winners!

**BEST PHARMACIST**
- **Jennifer Doran**
  Wegmans
  Wilkes-Barre, PA
- **Johnny R. Nobles III**
  Walmart Neighborhood Market
  Montgomery, AL
- **Vicki O’Connor**
  Osco
  Huntley, IL
- **Sue Ojageer**
  Walgreens
  McKinney, TX
- **Timothy M. Orcutt**
  Harris Teeter
  Fuquay-Varina, NC

**BEST PHARMACY TEAM**
- **Nho Nguyen**
  Kroger
  Houston, TX
- **Delaney Santon**
  Safeway
  Washougal, WA
- **Harris Teeter #341**
  High Point, NC
- **Safeway #1129**
  Dunkirk, MD
- **Charitable Pharmacy of Central Ohio**
  Columbus, OH

**BEST PHARMACY TECHNICIAN**
- **Digvijay Raol**
  Walgreens
  La Grange Highlands, IL
- **Jacqueline C. Tanzer**
  Walgreens
  Wilmington, DE
- **Tsehaye Zemenfes**
  Alamo Navajo Health Center
  Alamo, NM

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- **Jacqueline C. Tanzer**
  Walgreens
  Wilmington, DE
- **Tsehaye Zemenfes**
  Alamo Navajo Health Center
  Alamo, NM

**PHARMACY TECHNICIANS & INTERNS**
- **Haylee Truelove**
  Walgreens
  Valdosta, GA
- **Ingrid Zelenyanszky**
  Walgreens
  North Conway, NH
- **Nicholas Leeper**
  H-E-B
  San Antonio, TX
- **Nikki Smith**
  Walmart
  Fayetteville, AR
- **Haylee Truelove**
  Walgreens
  Valdosta, GA
- **Ingrid Zelenyanszky**
  Walgreens
  North Conway, NH

**PHARMACY TEAMS**
- **Weis #129**
  Damascus, MD
- **CVS #556**
  Gales Ferry, CT
- **Safeway #1129**
  Dunkirk, MD
- **Charitable Pharmacy of Central Ohio**
  Columbus, OH
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.
Introducing IN-DEPTH INSIGHTS:
1st Installment: Diabetes

Each installment will feature a comprehensive article on a trending counselling topic in pharmacy. Video insights from leading experts will complement each article with advice to help optimize your practice. The first installment will cover glycemic control counselling with an emphasis on proper injection technique.
Managing Metabolic Syndrome in Diabetes

Patients with metabolic syndrome and diabetes may be experiencing challenges outside medication management. By Keith Loria

Metabolic syndrome and diabetes are 2 of the most common diseases that pharmacists face in their daily practice. Because of this frequency, pharmacists play a vital role in reducing the burden for individuals living with these frequently comorbid conditions.

Phyllis Kamau, PharmD, a pharmacist with CVS Health, noted that the key for pharmacists working with patients who are dealing with metabolic syndrome and diabetes is to realize that patients frequently do not understand the relationship between the 2 conditions. Metabolic syndrome is characterized by abdominal obesity, high blood pressure, high blood sugar, elevated triglyceride levels, and low high-density lipoprotein cholesterol levels. A patient receives a diagnosis of metabolic syndrome if they meet 3 of these 5 criteria; having diabetes alone does not mean that the patient has metabolic syndrome—and vice versa. “There is a strong correlation, though, of having metabolic syndrome as a predictor of type 2 diabetes,” Kamau explained.

Michael P. Kane, PharmD, a professor at Albany College of Pharmacy and Health Sciences, noted that patients with metabolic syndrome typically have multiple comorbidities and therefore are taking several medications for multiple disease states. “It is important for patients to understand the importance of taking their medications as prescribed,” he said. “In addition, it is important for patients to know about appropriate lifestyle changes that can help manage these disease states. Patients need to be aware of potential adverse effects of medications and ways to mitigate or manage those adverse effects so that they can continue to better manage their diseases.”

And because patients often see the pharmacist monthly for medication refills—and therefore have access to their pharmacist more than their other health care providers—pharmacists are the best source of information regarding medications. This creates a wonderful environment for patient education and strategies to help patients better manage their diseases.

IMPORTANT CONVERSATIONS

According to Joyce Y. Lee, PharmD, a health sciences clinical professor of pharmacy at UC Irvine School of Pharmacy & Pharmaceutical Sciences, patients with metabolic syndrome and diabetes are frequently experiencing challenges beyond medications. Therefore, in addition to optimizing the 4Ds of medication management—drug safety, drug effectiveness, drug adherence, and dose titration—pharmacists must also focus on caring for patients as a whole, taking into account psychological and emotional needs, coaching individualized health behavior changes that last, and empowering patients’ self-care capabilities.

“Have an open-minded, nonjudgmental discussion with patients about their lifestyle and daily routines,” Lee said. “Emphasize the benefits of controlling metabolic syndrome and diabetes rather than the negative [aspects]. Point out areas that patients have done well in and areas that need further improvement. [Talk] with patients on strategies that have worked before and strategies that have not worked or are no longer working.”

Lee also recommended having patients propose a possible strategy to overcome the immediate problem. The pharmacist should provide suggestions and comment on the pros and cons of the strategy, modifying where needed to set a realistic timeline for strategy implementation.

Pharmacists should also be routinely screening patients’ profiles and recognize that most patients will be on medications for high blood sugar, blood pressure, and triglycerides—which is metabolic syndrome, although most patients will not know that.”Pharmacists should make it a point to counsel the patients on how lifestyle interventions could help to reverse these conditions, reducing their risk of cardiovascular disease and diabetes,” Kamau said. “The biggest challenge of counseling in retail is the time constraint. In most cases, there is not a lot of time for pharmacists to spend counseling a patient on how to manage their conditions. With a lot of intentionality, though, it can be done.”
Swathi Varanasi, PharmD, a pharmacy consultant in Los Angeles, California said one of the biggest challenges in the health care system is the overall unfamiliarity with getting to the root of the problem or thinking outside the box to solve a metabolic syndrome–related problem.

“This means asking probing questions with patience and understanding to figure out how to best help the patient improve their quality of life through not only their prescription medication regimen, but also their lifestyle,” she said. “An example is that the long-term use of metformin could lead to vitamin B12 deficiency. If a patient who has been prescribed and is regularly taking metformin... complains of fatigue or poor memory, addressing a vitamin deficiency through supplementation could be very helpful.”

For patients who do not wish to take metformin, asking key questions regarding diet, exercise, stress, sleep, caffeine, and self-care could be integral to their improvement. It could also help them in weaning off medications after they have reached an ideal hemoglobin A1c level.

“I have heard a lot of patients say that they were not aware of certain things when it comes to their health until the pharmacist mentioned it,” Kamau noted. “Pharmacists are able to recognize when the patients are not being [adherent to] their medications, and if they are incorrectly using or taking them.”

Lee feels it is also important to understand the health disparities in managing metabolic syndrome and diabetes among underserved populations.

“These patients’ challenges are often complicated by homelessness, mental illness, and poverty,” she explained. “Pharmacists are [in a] unique position to identify and look out for at-risk patients to ensure implementation of cost-effective therapies and access to eligible resources and technologies.”

“The biggest challenge of counseling in retail is the time constraint. In most cases, there is not a lot of time for pharmacists to spend counseling a patient on how to manage their conditions. With a lot of intentionality, though, it can be done.”

Phyllis Kamau, PharmD
From biosimilars to artificial intelligence, these are the trends poised to take community pharmacy by storm.

By Keith Loria
The pharmaceutical industry is ever changing. Many of these changes—be they biosimilars, new methods of medication delivery, or even new diseases having their moment in the research and development spotlight—will trickle down to the pharmacy level. It is important for community pharmacists to stay up to date on the latest and greatest innovations and advancements to continue providing the best care to their communities and patients.

“We are in an era where the velocity of scientific advancement is unlike another time in history, and the types of therapeutics being discovered and coming to market are revolutionary,” said Sonia T. Oskouei, PharmD, vice president of biosimilars at Cardinal Health. “From curative treatments with cell and gene treatments to the development of mRNA technologies for vaccines, this innovation is changing how we look at disease overall.”

The industry is also seeing growth in competition for innovator biologics that are critical to treating some of the most severe and chronic diseases via the growing biosimilar market.

With these changes, there is an increased demand and interest in elevating the role of community pharmacists, including in the education, advocacy and delivery of drugs. “This, I feel, is long overdue, given that full activation of pharmacists in communities is one of the strongest tools we have in expanding and extending patient care, enabling a more equitable and effective health care delivery system,” Oskouei said.
"We’re now watching biosimilars launch in ophthalmology and diabetes care."

SONIA T. OSKOUEI, PHARMD

Mergers and acquisitions are also having an impact on independent pharmacists. For example, Walgreens and Amazon have begun acquiring physician practices, and CVS recently announced it they will acquire Signify Health and its network of 10,000 clinicians across 50 states; the health tech platform helps organizations create value-based programs that increase metrics and keep patients healthy at home longer.

“Everyone is intrigued about the acquisitions that have been going on, and it’s becoming apparent that dispensing prescriptions alone is not enough to survive in the pharmacy industry while health care groups need to lean on pharmacy to better support metric goals and patient health,” said Lindsay Dymowski, CEO of Centennial Pharmacy Services.

“Organizations are starting to pair pharmacy with integrated health networks and utilize pharmacy to support value-based programs.”

More than perhaps ever before, policy activities are influencing how health care is delivered, from the Inflation Reduction Act of 2022 and the prescription drug pricing provisions to the Ensuring Innovation Act—all of which affect pharmacy and pharmacists.

Paige Clark, RPh, vice president of pharmacy programs and policy at Prescriptive Health, noted that one of the main policy actions affecting pharmacy this year is the Federal Trade Commission (FTC) investigation of pharmacy benefit managers (PBMs), announced on June 7, 2022. The investigation takes place amid growing pressure from legislators and the introduction of the bipartisan Pharmacy Benefit Manager Transparency Act of 2022 by Senator Chuck Grassley (R-Iowa) and Senator Maria Cantwell (D-Washington).

“We’re seeing an increased scrutiny of PBMs. If any regulation comes forth from the FTC probe, it will impact pharmacies greatly,” Clark said. “Independent pharmacies have long pushed for PBM reform because many believe their choice and influence have been severely limited with traditional PBM operations and contracts. For independent pharmacies in particular, it is even more imperative that they seek partners to offer profitable solutions. Traditional PBMs have significantly impacted ongoing profitability, so selecting a transparent PBM partner to assist in increasing pharmacy profitability is critical.”

New Medication Delivery Trends

Beckie Fenrick, PharmD, MBA, chief pharmacy officer at pharmacy benefits consulting firm AlignRx, noted that one of the most pressing issues in the industry today concerns gene therapy access and payment.

“While these treatments are truly unique and may bring benefit to certain impacted individuals, the cost for gene therapies easily exceeds $1 million,” she said. “Payment model innovation is needed to assure access. This might include regular insurance, installment payments, risk pool establishment, and outcomes-based contracts for the gene therapy.”

Gene therapies are utilizing new medication delivery trends. Voretigene neparvovec-rzyl (Luxturna) is one such prescription gene therapy that treats inherited retinal diseases caused by mutations in both copies of an individual’s RPE65 gene.6,7 The therapy utilizes a “viral envelope” to deliver the treatment; other gene therapies utilize the patient’s bone marrow stem cells to deliver the therapy.

Laura Cranston, a strategic growth consultant to Aspen RxHealth and CEO emeritus of Pharmacy Quality Alliance, noted that complex drugs are constantly coming to the market, requiring new and consistent counseling. New dispensing systems for high-cost drugs, especially those delivered via dispensing machines put in patient homes, are also something that is infiltrating the industry.

“Just because the device is in the patient home, they still need to know what to do if the device breaks,” Cranston said. “Some of the devices are used for $15,000 per month medications, where they can monitor down to the minute of the day the patient is taking it; but what about the education and persistence? Who better to do this than pharmacists?”

Pharmacy delivery, rather than pharmacy window pickup, is a growing trend in general. Community pharmacies are offering more transparent, reliable, and affordable delivery services to compete with mail-order pharmacies and give patients the convenience they want.

“Our world is starting to be more comfortable with everything being shipped or hand delivered, and medication is no exception. But patients still trust their local pharmacy...”
Drug Topics® October 2022

Biosimilars Gaining Traction
Biosimilars are developed with the promise of increasing access and lowering costs for biologic therapies, which represent the most expensive drug category in the world. By offering more options and interchangeability designation, the industry can further enhance patient accessibility to biologics at a lower cost through automatic substitution authority. Since biosimilars first launched in the US market in late 2015, the FDA has approved nearly 38 biosimilar products, 22 of which are commercially available as of August 2022. 

“Up until [2021], biosimilars had primarily been developed for the oncology and rheumatology therapeutic areas, but we’re now watching biosimilars launch in ophthalmology and diabetes care,” Oskouei said. “With this expansion, we are getting the opportunity to realize the benefits of biosimilars across other sites of care and moving into pharmacy benefits.”

Biosimilars are a great opportunity for pharmacists to educate and advocate for patients—even more so with the new interchangeability designation. “Interchangeability means that the biosimilar is expected to produce the same clinical result as the reference product in any given patient, which can be demonstrated through switching studies in which patients are switched between the reference product and the biosimilar multiple times,” Oskouei explained. “For products that gain this designation by the FDA, pharmacists may automatically substitute the branded biologic with the biosimilar—as done routinely with brand and generics—per state laws.”

Another massive trend is the adalimumab (Humira) shake-up. After more than 20 years of market exclusivity, adalimumab—once the best-selling drug in the world—will be facing competition with at least 6 biosimilars coming to market—something the health care industry is closely watching.

“Ultimately, bringing biosimilars to market enables pharmaceutical manufacturers to afford the next generation of innovative treatments, while also giving more access to patients,” Oskouei said. “With more biosimilars that fall under pharmacy benefits gaining FDA approval, we could see a huge increase in health cost savings, with some estimates that savings from biosimilars will increase to $133 billion by 2025.”

Pharmacists will play a key role in the advocacy of biosimilars as more come to market and more patients begin to use them. “As the number of biosimilars grows, pharmacists can play a key role in assuring their uptake by ensuring patients understand that biosimilars are not generics and that they undergo extensive testing before they are granted FDA approval,” Fenrick said. “That testing assesses that there are no significant differences between the original reference product and the biosimilar.”

Looking Ahead
From a retail pharmacy perspective, the evolving reimbursement model for Medicare Part D from primarily a direct and indirect remuneration fee perspective to point-of-sale discounts is something that many pharmacists are paying attention to. “There will be more transparency for [pharmacists] around drug reimbursement, but the reimbursement pressure will likely still be there,” Dymowski said. “Thus, retailers will need to evolve again from a fee-for-service model to ultimately a value-based provider, where medical is heading.”

Clark noted that bringing technology to pharmacies nationwide is a tremendous opportunity to empower consumers and patients. For example, artificial intelligence can help pharmacies stay competitively priced while still providing value for consumers, making them more successful in expanding what they are able to do for patients in community settings.

“The consumer side, they want modern communication with their pharmacists, so pharmacies will need to adapt accordingly,” Clark said. “In fact, 47% of consumers rated technology as a top requirement for retaining their business, even more than being the lowest-cost pharmacy.”

For references, visit drugtopics.com.
Closing the Historic Routine-Vaccination Gap

Pharmacists can play a key role in helping to improve backsliding vaccination rates. By Sandra Fyfe

On July 15, 2022, the World Health Organization (WHO) reported the largest decrease in routine vaccinations in 30 years. In 2021, 25 million infants worldwide missed routine vaccinations and 2.6 million children in the United States were unvaccinated or not up to date on their vaccines.  

The steep decline has health officials on alert. In the news release, the WHO said the DTP3 (diphtheria tetanus toxoid and pertussis) vaccination rate, a touchstone for vaccination coverage rates, fell 5% between 2019 and 2021 to 81%, resulting in 25 million children missing 1 or more doses. In the Americas—where reported rates of routine vaccinations for rubella, measles, polio, and diphtheria have been steadily declining over the past 10 years—the pandemic has only made things worse. Human papillomavirus (HPV) vaccination has also steeply declined: More than 25% of the coverage of HPV vaccines achieved in 2019 has been lost.  

The causes for the historic decrease in vaccination rates, according to the WHO, included COVID-19 containment measures that blocked access to health care services, supply chain issues, resource diversion, vaccine misinformation, service disruptions, and more children residing in conflict or fragile zones where vaccines could not reach them.  

Brigid Groves, PharmD, MS, senior director of practice and professional affairs at the American Pharmacists Association (APhA) in Washington, DC, spoke with Drug Topics® to explain how pharmacists can help close the vaccination gap exacerbated by the COVID-19 pandemic. Closing this gap, she said, is essential because in addition to lower rates of routine vaccinations causing a resurgence in diseases, “there is a particular danger to immunocompromised patients who rely on herd immunity for coverage.”

Barriers to Implementing Vaccination  
Pharmacists are well positioned to help improve vaccination rates, but barriers do exist, Groves noted. “Depending on the state, there are different protocols and legislation in place regarding the administration of vaccines,” she said. “There are inconsistencies among which vaccines can be given to which age groups, where, and by whom.” Pharmacists should confirm local rules and regulations with their state pharmacy practice acts to ensure training and compliance, she said.  

Another barrier is vaccine hesitancy among patients. According to Groves, a major contributor to hesitancy has been misinformation that was already circulating before the pandemic and then became worse over the past 2 years.

How Pharmacists Can Increase Vaccination Rates  
Groves shared several ways that pharmacists can assist in closing gaps in vaccination. She said some states allow pharmacists to access immunization records, and having that information readily available is one way to assess immunization gaps for individual patients.  

Another way pharmacists can increase rates of vaccination is to connect and collaborate with local communities, Groves said. “Pharmacists can be especially helpful in

“Scientific studies can be overwhelming for patients. Pharmacists can distill data into patient-friendly, understandable language to educate patients of the importance of being up to date on vaccination.”

BRIGID GROVES, PHARMD, MS
communities that don’t have other health care providers or locations nearby to get the vaccinations they need,” she explained. This includes public health entities and other providers, especially for pediatric and adolescent patients. “Pharmacists are extenders of care to make services more accessible to families when they connect with health care providers,” she said.

Groves also suggested that pharmacists think outside the box and coordinate to offer vaccinations in a local facility space where other providers such as pediatricians can be invited to attend. “Pharmacists can then create a fun and engaging atmosphere, using stickers or other novelty items to encourage children to feel comfortable,” she said.

Pharmacists can also discuss vaccines with patients when they pick up prescriptions. This point-of-care technique prevents patients from having to make an appointment and additional trip, Groves said. That contact in the pharmacy also provides an opportunity to fight misinformation. “Having conversations with families, caregivers, and patients can reduce misinformation and increase rates of vaccination,” she noted.

“Scientific studies can be overwhelming for patients. Pharmacists can distill data into patient-friendly, understandable language to educate patients on the importance of being up-to-date on vaccinations.

“Pharmacists know the appropriateness of the vaccine for the patient, the timing of doses, and any contraindications that would preclude the patient from being eligible for that particular vaccine,” Groves continued, adding that pharmacists also are excellent at counseling patients and making sure they have opportunities to ask questions, which is especially important for concerned parents of pediatric patients.

For references, visit drugtopics.com.

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**Respiratory**

**Stay Informed With the Latest Influenza Data**

A new web feature will provide up-to-date influenza information in an easy-to-read format.

By Miranda Hester

The verdict is in: Reports from the Southern hemisphere indicate that the Northern hemisphere may be in for a challenging 2022-2023 influenza season.1 Australia has had its worst season in 5 years, with cases peaking at 3 times higher than average, according to government surveillance reports.2

As states across the United States continue to lift mask mandates, workers head back to the office, and children return to school, there is heightened concern that the 2022-2023 influenza season will be a rough one. In addition, government models predict COVID-19 cases will peak again in December.1 For pharmacists, knowing the latest surveillance data is crucial to helping keep communities safe.

The Drug Topics team is publishing a weekly influenza update to help keep our readers current. This easy-to-read infographic sources data from FluView, the CDC’s weekly influenza surveillance report.3 It includes the number of laboratory-confirmed influenza cases, outpatient visits, hospitalizations, and pediatric deaths that have occurred, plus insight into which states are seeing very high activity levels.

To see the latest infographic (and our other influenza resources), visit drugtopics.com/clinical/influenza or scan the QR code.

For references, visit drugtopics.com.

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For references, visit drugtopics.com.
Mental, Behavioral Health Issues
Call for Creative Solutions

In an ideal world, pharmacists would be able to spot patients in mental health crisis and provide appropriate solutions.  

By Meg Marzella

What if pharmacists could help prevent suicide? One Iowa pharmacy may have done just that.

Kate Gainer, PharmD, executive vice president and CEO of the Iowa Pharmacy Association (IPA) shared her story during a presentation focused on creative mental and behavioral health solutions at the National Association of Chain Drug Stores Total Store Expo, held August 27 to 29 in Boston, Massachusetts, alongside Erin Shaal, PharmD.

“I asked a pharmacist to administer the [Patient Health Questionnaire-9] in a pharmacy in central Iowa. The results were that the patient was suicidal.... Before the patient left the pharmacy, the pharmacist was able to contact a case manager... and get them on the phone as the patient was walking out the door. And the pharmacist was able to provide follow-up and make sure that that care linkage existed.”

In an ideal world, all pharmacists would be able to spot similar situations and provide appropriate care. In a country where 52.9 million individuals are living with mental illnesses, more solutions for screening for mental health—and helping patients cope—are desperately needed.

During their session, Shaal and Gainer presented a handful of creative solutions during their session that can help combat the current mental health crisis while providing the most acute care to patients struggling with mental illness.

Screening Questionnaires

Shaal, vice president, pharmacy procurement, specialty and patient care at Albertsons Companies, pointed out that questionnaires are a quick and easy way to measure a patient’s health. Pharmacists can use questionnaires to help identify mental or behavioral health issues that a patient is facing—and a simple questionnaire administered when a patient is in the pharmacy for another service, can alleviate the stigma and create an avenue for a conversation about mental health.

Upstream Intervention

The goal of upstream intervention is fighting the problem at the source; in other words, working to figure out why so many individuals are facing mental health issues in the first place.

At the University of Iowa, medical students created an “upstream clinic” focused on social determinants of health (SDOH). Students working at the clinic would provide an SDOH questionnaire to patients to determine whether there were any needs related to food, transportation, legal services, or family issues not being addressed that could be affecting their health.

Using the results of the questionnaire, clinic staff were able to determine what kinds of help patients needed, other than the medical help they were at the clinic for. Staff then went on to fill those gaps by providing food, transportation, legal services, and much more.

Mental Health First Aid and Trauma-Informed Care

Just as CPR is needed if someone is having a heart attack, mental health first aid is needed when someone is having a mental health crisis. Mental health first aid is training to identify, understand, and respond to someone dealing with a mental health issue. Perhaps most important is that like CPR, this training isn’t just for pharmacists and pharmacy staff members; widespread mental health first aid training can help all of us take care of each other, Gainer pointed out.

Similarly, the goal of trauma-informed care is addressing patients or clients with the notion that they may be dealing with some form of trauma. Using the right language, and having the right tools under their belt, can help pharmacists more effectively communicate with patients who are dealing with trauma.

In the fight against the current mental health crisis, pharmacies and pharmacists help patients identify and cope with their mental and behavioral issues, it may just require a little bit of creative problem solving.

“I think that pharmacists should play a role in advocacy and support, and really be that front line,” Gainer said. “And recognition of the fact that there’s additional sources out there for them. There’s additional resources, there’s different health, there’s different education, that you don’t necessarily have to do it alone.”

A content source designed specifically for pharmacy industry professionals practicing in (or interested in moving to) an independent pharmacy, Total Pharmacy® provides trusted resources and actionable business solutions to effectively maximize profitability, minimize costs, and improve the patient experience.
Follow the Money

As he prepared to move house, our columnist was struck by the similarities between a yard sale and the prescription drug pricing infrastructure.

Simply put, one of the biggest challenges of moving from one house to another is what to do with all the stuff. We decided to move from central Pennsylvania to Morgantown, West Virginia, to live closer to our daughter, her husband, and our adorable 6-year-old grandchild. This move also put us 1 hour closer to Pittsburgh, Pennsylvania, where my son, his wife, and our 2 beautiful granddaughters live.

We had lived in our home for 36 years, and we raised 3 children there. When raising 3 active kids, you accumulate a lot of stuff: 4 canoes, a canoe trailer, yard decorations, and numerous bicycles all filled the extra garage I rented downtown. Knowing we could not possibly bring all this stuff to Morgantown, we had to sell it. What was all this stuff worth? Whatever the next person would pay for it!

At our yard sale, my canoe trailer brought me $250—more than I’d paid for it 20 years ago—and the canoes did equally well. However, small kitchen appliances were hauled away for pennies on the dollars. We were just glad for the major downsize. We had priced items reasonably, but to keep in the game, we discounted everything when the buyers asked for a deal.

This process reminds me of what I do every day in the pharmacy. When I look at the 5 biosimilars of insulin glargine, ranging from $144.28 to $405.41 for the brand name, I am amazed that not a single patient has the least expensive biosimilar on their formulary. Instead, the most expensive brand is preferred. Could you imagine going to the grocery store and seeing cans of pineapple priced from $1.44 to $4.05, and everyone buying the most expensive can?

Unfortunately, this happens in the pharmacy every day. We are acutely aware that brand-name therapies have grossly inflated prices to help cover the offered rebates. We know full well that there is not a pharmacy benefit manager (PBM) or insurance company paying the full $405.41 for brand-name insulin glargine. PBMs blame drug companies, drug companies blame PBMs, and patients blame pharmacists, as we are the only ones that they can complain to. Yet 3 PBMs process 79% of the prescriptions filled on a daily basis.

According to the National Community Pharmacists Association, “PBMs raise drug costs by almost 30% due to the rebates they charge manufacturers to be on their formularies. PBM rebates, at $143 billion in 2019, add nearly 30 cents per dollar to the price consumers pay for prescriptions.”

Over the years, I have learned that when something doesn’t make sense, follow the money. My yard sale netted us some nice money; fortunately, we didn’t have to contribute to a political action committee or give anything to a middleman. I wish the government could operate health care with such a simplistic game plan.

Drugs are worth what the next patient will pay for them, just like my canoes, step ladder, and ice fishing equipment. And as long as someone else is picking up the tab, drug prices will continue to escalate, while the PBMs continue to take advantage of pharmacies, the government, drug companies, and—of course—patients.

For references, visit drugtopics.com

Peter A. Kreckel, RPh, practices community pharmacy in Lemont Furnace, Pennsylvania.
hypertrophic cardiomyopathy (HCM) occurs when the walls of the left ventricle become enlarged and thicken. In obstructive HCM, impaired blood flow in the heart can result in chest pain, dyspnea, syncope, and edema. Untreated HCM can lead to atrial fibrillation, stroke, or heart failure (HF). Although current treatments may help relieve symptoms, they do not address the underlying pathology. Mavacamten, the first-in-class cardiac myosin inhibitor approved by the FDA in April 2022, prevents myosin-actin cross-bridge formation in cardiac muscles, targeting the pathophysiology of obstructive HCM. By reducing cardiac contractility and dynamic left ventricular outflow tract (LVOT) and improving cardiac filling pressures, mavacamten improves functional capacity and symptoms in adults with New York Heart Association (NYHA) class II-III obstructive HCM.

**Efficacy**

Investigators for the phase 3, double-blind, randomized, placebo-controlled, parallel-group EXPLORER-HCM clinical trial (NCT03470545) enrolled 251 adult participants with symptomatic (NYHA class II or III) obstructive HCM, and with a left ventricular ejection fraction (LVEF) of 55% or greater and LVOT peak gradient of 50 mm Hg or greater at baseline. For 30 weeks, each patient received either mavacamten or placebo. The primary study end point was composite, examining clinical response at week 30; this was defined as an increase of 1.5 mL/kg/min pVO$_2$ or greater plus an improvement of 1 or higher in NYHA class, or an increase of 3.0 mL/kg/min pVO$_2$ or greater and an unchanged NYHA class.

At week 30, 37% of patients in the mavacamten group met the primary end point vs 17% in the placebo group. The mavacamten group also demonstrated improvements in all secondary end points vs placebo; these end points and differences between the 2 groups included postexercise LVOT gradient (–35.6), pVO$_2$ (1.4), and NYHA class (34% more patients improved by at least 1 class).

Improvements in patient-reported outcomes measured by the Kansas City Cardiomyopathy Questionnaire-Clinical Summary Score and Hypertrophic Cardiomyopathy Symptom Questionnaire score for shortness of breath were also higher with mavacamten therapy.

**Safety**

Overall, patients in the EXPLORER-HCM trial tolerated mavacamten well; in the placebo group, patients more frequently experienced dizziness (27% vs 18%) and syncope (6% vs 2%).

Mavacamten has a boxed warning for HF risk due to systolic dysfunction and is only available through the Camzyos Risk Evaluation and Mitigation Strategy program. Prior to treatment, patients must undergo an echocardiogram to assess LVEF. If LVEF is less than 55%, treatment is contraindicated; if LVEF is less than 50% or HF symptoms occur, treatment should be held. During treatment, LVEF should be tested at every 4 weeks initially and every 12 weeks once the maintenance dose has been established. Concomitant mavacamten and disopyramide use with either verapamil or diltiazem is also associated with increased HF risk. Mavacamten is contraindicated with moderate to strong cytochrome P450 (CYP) 2C19 inducers and inhibitors, moderate to strong CYP3A4 inducers, and strong CYP3A4 inhibitors.

**Dosing**

Mavacamten is available as 2.5-mg, 5-mg, 10-mg, and 15-mg once-daily capsules. The recommended starting dose is 5 mg; titration is based on Valsalva LVOT gradient targets and LVEF assessments. If LVEF decreases below 50%, treatment should be interrupted. After 4 weeks, if LVEF is 50% or greater, treatment may be restarted at a lower dose. Patients can take mavacamten with or without food; capsules should not be crushed, chewed, or opened. Close monitoring is recommended when initiating other medications that are CYP2C19 or CYP3A4 substrates.
Prescribed Medications
Pharmacogenomics and Commonly disclosed.
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An anonymous peer reviewer was part of the content validation and conflict resolution and has no relevant financial relationships with commercial interests to disclose.

EDUCATIONAL OBJECTIVES
At the completion of this activity, the participant will be able to:
• Review those medications among the top 200 most commonly prescribed that have pharmacogenomic relationships as noted in clinical guidelines and/or FDA resources.
• Discuss the context of pharmacogenomics related to the specific medications.
• Review the pharmacogenomic relationships that directly impact medication selection and/or dosing.

TARGET AUDIENCE: Pharmacists
ACTIVITY TYPE: Knowledge
RELEASE DATE: October 10, 2022
EXPIRATION DATE: October 10, 2023
ESTIMATED TIME TO COMPLETE ACTIVITY: 2.0 hours
FEE: This lesson is offered for free at www.advancepharmacist.com

Introduction
In 2016, the Accreditation Council for Pharmacy Education (ACPE) standards for pharmacy education included genetics/genomics. Competencies in genetics/genomics have recently been published that address the profession’s expectations of the pharmacist’s role in pharmacogenomics (PGx). PGx can play a critical role in individualizing and optimizing medication efficacy while minimizing or avoiding adverse drug reaction altogether. PGx is an example of precision medicine that refers to how a person’s DNA/genetics affects how they respond, or do not respond to a medication.

DNA, the genetic makeup of an individual, contains 2 twisting paired strands made up of 4 chemical bases called nucleotides: adenine (A), cytosine (C), guanine (G), and thymine (T). Adenine always pairs with T and C always pairs with G. In each nucleus-containing cell, the individual’s DNA is found in 2 sets of chromosomes. Each set contains 23 chromosomes with 1 set being provided by each parent. Thus, there are a total of 46 chromosomes in cells containing a nucleus. Interindividual differences in DNA are described as genetic variation, and while there are different types of genetic variation, the most common form of variation is the single nucleotide polymorphism (SNP, pronounced “snip”), where 1 nucleotide base in a sequence replaces another, such as T replacing a G at a specific locus in the DNA sequence. Each SNP is assigned a specific reference identification, or reference SNP number (rs#). In the DNA sequence, each trio/triplet of nucleotide bases is called a codon, which codes for the making of an amino acid. Therefore, the DNA sequence results in an amino acid sequence, which upon folding, may form a specific protein, such as an enzyme that metabolizes medications, a transporter that moves or excretes medications, or a receptor/other gene product related to an individual’s response to a medication (ie, a pharmacogene product).

An individual inherits their DNA from each parent. As an example, one parent may pass along the DNA that will code for a cytochrome P450 enzyme, such as CYP2C19, that has “normal function.” The other parent may contribute DNA that will code for a “no-function” form of CYP2C19, where G is replaced by A at a specific locus on chromosome 10. Here, the individual’s
genotype would be G/A, and they would have an altered metabolic function of CYP2C19 because they possess 1 normal function form and 1 “no function” variant that results in reduced CYP2C19 enzyme activity compared with an individual with 2 normal function forms. Of note, an italicized designation (eg, CYP2C19) refers to the gene. The designation is not italicized (eg, CYP2C19) when referring to the gene product, such as a drug-metabolizing enzyme as described in the above example. The star allele “*” nomenclature has been adopted to help with consistency in presenting PGx information. The nomenclature has been applied to many drug-metabolizing and transporter genes, but is not used for all pharmacogenes. Currently for CYP2C19, there are more than 35 * forms or alleles. The *1 allele is a common “normal function” form, whereas the *2 and *3 alleles are “no function” forms, with *2 being more common than *3. There are different numbers of gene forms that have been identified for the various pharmacogenes. For instance, as of July 2022, there were more than 80 forms of CYP2C9 and almost 150 forms of CYP2D6. The different gene forms may include a number of genetic variants (eg, SNPs) that are inherited together. The technical term for this is “haplotype.” For instance, CYP2C19*2 includes 4 SNPs. The combination of star alleles (haplotypes), one from each parent, eg, CYP2C19 *1/*2, are called a diplotype. The observable characteristics of an individual’s genotype/diplotype, which is a product of how the 2 haplotypes are expressed, is called a “phenotype.”

There are now standardized terms for metabolism phenotypes as well as transporter phenotypes (see Table). These phenotypes are directly related to therapeutic recommendations in PGx guidelines. It should be noted that there are valid PGx guidelines that use older terms, which were published before the standardization of terms.

To view the entire CE activity and references, please go to www.advancepharmacist.com/pharmacogen or scan the QR code.

### Table. Standardized Phenotype Terms and Definitions for Drug Metabolizing Enzymes and Transporters

<table>
<thead>
<tr>
<th>PHENOTYPE</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolism</td>
<td></td>
</tr>
<tr>
<td>Ultrarapid metabolizer (UM)</td>
<td>An individual with 2 increased function genetic variants, or more than 2 normal function forms, as with gene duplication or multiplication.</td>
</tr>
<tr>
<td>Rapid metabolizer (RM)</td>
<td>An individual with a combination of a normal function form and an increased function variant.</td>
</tr>
<tr>
<td>Normal metabolizer (NM)</td>
<td>An individual with 2 normal function forms.</td>
</tr>
<tr>
<td>Intermediate metabolizer (IM)</td>
<td>An individual with a combination of a normal function form and decreased function or no function genetic variant.</td>
</tr>
<tr>
<td>Poor metabolizer (PM)</td>
<td>An individual with a combination of no function genetic variant and/or decreased function genetic variant.</td>
</tr>
<tr>
<td>Transport</td>
<td></td>
</tr>
<tr>
<td>Increased function</td>
<td>An individual with 1 or more increased function genetic variants.</td>
</tr>
<tr>
<td>Normal function</td>
<td>An individual with combinations of normal function form and/or decreased function genetic variant.</td>
</tr>
<tr>
<td>Decreased function</td>
<td>An individual with combinations of normal function form, decreased function genetic variants, and/or no function genetic variants.</td>
</tr>
<tr>
<td>Poor function</td>
<td>An individual with a combination of no function genetic variants and/or decreased function genetic variants.</td>
</tr>
</tbody>
</table>
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Important Safety Information

EPRONTIA™ (topiramate) oral solution, 25 mg/mL

Indications:
• Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older.
• Adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.
• Preventive treatment of migraine in patients 12 years of age and older.

Inform patients that a calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device.

Additional Important Safety Information

Warnings and Precautions:
Acute Myopia and Secondary Angle Closure Glaucoma: A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving EPRONTIA (topiramate). Symptoms typically occur within 1 month of initiation of EPRONTIA therapy. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Ophthalmologic findings include myopia, anterior chamber shallowing, ocular hyperemia (redness), and increased intraocular pressure. Primary treatment to reverse symptoms is discontinuation of EPRONTIA.

Visual Field Defects: Visual field defects have been reported in clinical trials and post-marketing experience in patients receiving topiramate. In clinical trials, most of these events were found to be reversible after topiramate discontinuation. If visual problems occur, consideration should be given to discontinuing the drug.

Oligohydrosis (decreased sweating) and Hyperthermia:
Patients treated with any AED should be monitored for the emergence or worsening of cognitive-related dysfunction (confusion, difficulty with concentration, speech problems, in the skin). Antiepileptic drugs (AEDs), including EPRONTIA, may increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any AED should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Cognitive/Neuropsychiatric Adverse Reactions: EPRONTIA can cause cognitive/ neuropsychiatric adverse reactions. The most frequent adverse reactions can be classified into 3 categories: 1) cognitive-related dysfunction (confusion, difficulty with concentration, difficulty with memory, speech or language problems); 2) psychiatric/behavior disorders; 3) somnolence or fatigue.

Fetal Toxicity: EPRONTIA can cause fetal harm when administered to pregnant women. The benefits and risks should be considered when administering this drug in women of childbearing potential.

Withdrawal of Antiepileptic Drugs: EPRONTIA should be gradually withdrawn to minimize the potential for seizures or increased seizure frequency. If rapid withdrawal is required, appropriate monitoring is recommended.

Serious Skin Reactions: Serious skin reactions (Stevens-Johnson Syndrome [SJS] and Toxic Epidermal Necrolysis [TEN]) have been reported. EPRONTIA should be discontinued at the first sign of a rash unless the rash is clearly unrelated to the drug. If signs or symptoms suggest SJS/TEN, use of this drug should not be resumed and alternative therapy should be considered. Inform patients about the signs of serious skin reactions.

Hyperammonemia and Encephalopathy (Without and With Concomitant Valproic Acid Use): Topiramate treatment can cause hyperammonemia with or without encephalopathy, the risk of which appears to be dose related, and which has been reported more frequently with concomitant use of valproic acid. In patients who develop unexplained lethargy, vomiting, or changes in mental status associated with topiramate, hyperammonemic encephalopathy should be considered and an ammonia level should be measured.

Kidney Stones: EPRONTIA can cause an increased risk of kidney stones. The concomitant use of topiramate with any other drug producing metabolic acidosis, or potentially in patients on a ketogenic diet, may increase the risk of kidney stone formation. Instruct patients to stay well hydrated while taking EPRONTIA.

Hypothermia with Concomitant Valproic Acid Use: Hypothermia has been reported in association with topiramate use with concomitant valproic acid both in conjunction with hyperammonemia and in the absence of hyperammonemia. Consider discontinuation of topiramate or valproate in patients who develop hypothermia. Blood ammonia levels should be assessed during clinical management.

Adverse Reactions:
The most common side effects for EPRONTIA include:
• Tingling of the arms and legs
• Not feeling hungry
• Nausea
• A change in the way foods taste
• Diarrhea
• Weight loss
• Dizziness
• Sleepiness/drowsiness
• Slow reactions
• Difficulty with memory
• Pain in the abdomen
• Fever
• Abnormal vision
• Decreased feeling or sensitivity, especially in the skin

These are not all the possible side effects of EPRONTIA.

Use in Specific Populations:

Women of Reproductive Potential
Women of childbearing potential who are not planning a pregnancy should use effective contraception because of the risks of oral clefts and small for gestational age (SGA).

Renal Impairment
The clearance of EPRONTIA is reduced in patients with moderate (creatinine clearance 30 to 69 mL/min/1.73 m²) and severe (creatinine clearance <30 mL/min/1.73 m²) renal impairment. A dosage adjustment is recommended in patients with moderate or severe renal impairment.

Patients Undergoing Hemodialysis
EPRONTIA is cleared by hemodialysis at a rate that is 4 to 6 times greater than in a normal individual. A dosage adjustment may be required.

The important Safety information does not include all the information needed to use EPRONTIA safely and effectively. Visit EPRONTIA.com for full prescribing information.

To report SUSPECTED ADVERSE REACTIONS, contact Azurity Pharmaceuticals, Inc. at 1-855-379-0383, or FDA at 1-800-FDA-1088 or www.fda.gov/MedWatch.

HCP-EPR-1.6
Dear Fellows and Members of the American College of Apothecaries,

Make plans now to attend the ACA | ACVP | PPHI Annual Conference and Expo, February 22-25, 2023 at the luxurious Wyndham Grand Rio Mar in beautiful Puerto Rico.

Last year’s attendees agreed that our first opportunity to gather in-person was a success! Here’s what they had to say:

- Beautiful hotel and beautiful setting. Conference was smoothly run.
- Excellent meeting!!! It was such a nice way to have conferences back in person.
- Everyone was great—all the staff. Thanks!
- Excellent
- Well organized
- Wonderful experience
- All ACA staff managing this event are wonderful
- Terrific conference considering that Covid had not yet diminished and here were many restrictions / mandates. Looking forward to ACE 2023!
- I went away with actionable ideas that I can implement in my pharmacy on Monday
- Great inside info and real world experiences
- Excellent presentation.
- Very knowledgeable and interesting speaker!

Registration opens October 1, 2022 at acainfo.org/ace and not only do we have an outstanding slate of speakers, we are adjusting our schedule to ensure that you don’t miss a single educational session. Plus, we’re bringing back more opportunities for attendees to interact on hot topics outside of the CE room, with This Works for Me! Talks during breakfast, special presentation opportunities during an extended lunch break, and wrap-up roundtables to close out the afternoons.

We can’t wait to see you in Puerto Rico!