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Preparing for Evolving Pharmacist Roles

At the beginning of 2020, we provided a look into the upcoming trends that will shape how the profession moves forward in the year ahead. But what if we dig even deeper? What new gaps will pharmacists need to fill?

Walk into a pharmacy in 2030 and you may find that the pharmacist’s role has completely transformed. Our cover story for this issue explores what the future will bring as pharmacists move beyond their dispensing duties and continue to step out from behind the counter, exploring the evolution of new roles and specialized niches emerging in the profession.

March is National Autoimmune Disease Awareness Month, and this issue provides an update on multiple sclerosis (MS) treatment options, management tips, and what’s in the pipeline. Approximately 1 million individuals are living with MS in the United States. Pharmacists can play an integral role in managing the disease in their patients.

In preparation for allergy season, in this issue Frieda Wiley, PharmD, discusses recommended products and drugs for patients looking to relieve their allergy-related symptoms, as well as counseling tips and techniques for optimizing these treatments. In addition, pharmacists looking to add diabetes care to their expertise will find advice on page 14 on how to turn their pharmacy into a place where patients seek out care and counseling for their disease.

Feeling like you could use a change in your profession or you’re just not the right fit for a current job? This issue also features an article on how to make a career pivot to explore a different path in pharmacy. Pharmacy managers and educators offer expert advice on transitioning into different areas of the field—sharing knowledge that is applicable to both graduating students and established pharmacists.

It’s easy to get caught up in the stresses of the job; sometimes you just need to reflect on what motivated you to join the profession in the first place. Karen Berger, PharmD, asked pharmacists from across the country, and a variety of settings, why they became a pharmacist. Their answers are refreshing and motivating.

As Laura Dee, PharmD, clinical pharmacist, said in the article, “pharmacy as a profession is very versatile—you can do research, or work in a hospital, industry, or retail. You are also learning something new every day—as our society evolves, so does our profession.”

Thank you for reading and continue to follow us on DrugTopics.com for more.

Mike Hennessy, Sr.
Chairman and Founder
of MJH Life Sciences
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.
A new study published in *JAMA Network Open* found that an Ohio law allowing pharmacists to dispense naloxone without a prescription was linked to a significant increase in naloxone dispensing rates, especially in low-employment areas, according to the researchers.

For the study, the researchers analyzed naloxone dispensing rates after the implementation of the state law using Ohio Medicaid naloxone claims and Kroger Pharmacy naloxone claims for all counties in Ohio. Overall, in the Ohio Medicaid population, the number of naloxone orders dispensed in the post-policy period increased by 2328%, from 191 in the pre-policy period to 4637 in the post-policy period. Additionally, the number of orders dispensed by the 3 large chain community pharmacies increased by 3237%, from 59 in the pre-policy period to 1969 in the post-policy period, according to the study.

The results also showed that patients residing in a low-employment county were significantly more likely to receive naloxone in the post-policy period (11.5%) compared with the pre-policy period (3.8%; P=.001). Individuals in high-poverty counties were also significantly more likely to receive naloxone in the post-policy period (13.6%) compared with the pre-policy period (6%; P=.003).

The study authors noted that pharmacists are able to provide medication-assisted treatment and can work with the health care team to optimize pain treatment. Identifying and educating patients who might benefit from the protocol is key, they said.
New Reports Show Skyrocketing DIR Fees

Two new reports quantify the problem that community pharmacists have experienced firsthand: direct and indirect remuneration (DIR) fees are skyrocketing. DIR fees have increased by 1600% in the last 5 years, totaling $8.5 billion since 2013, according to a new policy analysis from XIL Consulting. Pharmacy benefit managers (PBMs) are profiting from DIR fees in excess of 500% per prescription, compared with the average PBM administration fee, XIL noted.

“Rural pharmacies have been impacted tremendously with a 16% reduction since the introduction of the Medicare Part D program. Fifty-one percent of these rural communities are now considered pharmacy deserts,” XIL said.

From January 2014 through December 2019, the most commonly used brand drugs experienced list price inflation of 70.5%.

Express Scripts Report Highlights Top Drug Classes Driving Spending

Therapies for inflammatory conditions accounted for nearly half of spending among different drug classes for commercial drug plans in 2019, according to a new Express Scripts Drug Trend Report. The report found that drugs for this therapeutic area drove 43.7% of spending, likely due to the shift toward newer, more expensive brand alternatives, with a 17.1% spending increase from 2018.

Specialty drug spend accounted for the greater share of total spend than in 2018. Specialty drug costs continue to inch toward nearly half of all spending on prescription drugs, increasing from 44.7% in 2018 to 47.7% in 2019, the report found.

The analysis, which is released annually by pharmacy benefit manager (PBM) Express Scripts, highlights trends in drug spend, defined as year-over-year percent changes in per-member-per-year (PMPY) spending on prescription drugs, inclusive of self-administered specialty drugs paid under the pharmacy benefit.

Express Scripts Report Highlights Top Drug Classes Driving Spending

From January 2014 through December 2019, the most commonly used brand drugs experienced list price inflation of 70.5%.

From July 2018 to July 2019, the number of pharmacies nationally have decreased by 3.8%.

From October 1, 2019 to February 8, 2020, there have been an estimated:

- **Flu Illness**: 26-36 million
- **Flu Hospitalizations**: 250,000-440,000
- **Flu Deaths**: 14,000-36,000

Source: CDC

**Millennials Are Least Likely To Receive Flu Vaccine**

Millennials are the least likely age group to receive the flu vaccine, according to a new survey commissioned by the American Academy of Family Physicians (AAFP).

The survey was conducted by Wakefield Research between November 27 and December 9 and included feedback from adults between the ages of 25 to 73 years old.

During the survey, participants were asked about a series of facts and myths about influenza to gauge their knowledge. At least 86% of millennials got at least 1 of the facts incorrect and nearly a third (31%) got all of the facts incorrect.

Fifty-five percent of millennials who were surveyed had not received the flu vaccine this year and a third of those had no plans to be vaccinated, according to the AAFP. Millennials were twice as likely as other groups to say they had not gotten the vaccine because they forgot.

The age group was also found to be the least-informed group about the risks of influenza and more likely to agree with anti-vaccination beliefs.

**FLU ILLNESS**  
26-36 MILLION

**FLU HOSPITALIZATIONS**  
250,000-440,000

**FLU DEATHS**  
14,000-36,000

Source: CDC
A new Kaiser Permanente primary care model utilizes pharmacists and pharmacy technicians, detailed in a recent issue of Harvard Business Review. The program, designed for treating patients with multiple chronic diseases, uses technology and medical staff to provide expanded support to primary care physicians, allowing pharmacists to access laboratory data and make many of the medication changes needed. The model is already implemented in California, Virginia, Maryland, and the District of Columbia, and “significantly reduces costs and improves the quality of care,” according to Harvard Business Review.

Adolescents, Young Adults with HIV Have Lower Viral Suppression Rates

Youth with newly-diagnosed HIV are less likely to achieve viral suppression compared with adults, indicating a need for better interventions tailored toward adolescents and young adults, according to a new study published in the Journal of Acquired Immune Deficiency Syndrome.

The study, which used a large national sample of predominantly newly-diagnosed youths, found that individuals aged 13 to 24 years of age diagnosed with HIV achieved disproportionately lower rates of viral suppression. More than 1000 individuals, most of whom were newly enrolled in care at treatment centers, were included in the analysis. Of the 1411 individuals in the study, 75% were linked in, 59% engaged in, and 34% retained in care at adolescent health care sites. Thirty-four percent initiated antiretroviral therapy (ART) and 12% achieved viral suppression, according to the study.

Predictors of viral suppression included lower viral load at baseline, recent ART receipt, and shorter time from HIV testing until referral to linkage coordinate.

Compared with youth referred to care after 3 months, those referred within 1 to 6 weeks were 2.5 times more likely to reach viral suppression. Those referred from 6 weeks to 3 months were roughly twice as likely to reach viral suppression, according to the authors.

According to the authors, prompt referral to youth-friendly linkage services impacted viral suppression. The authors suggested that youth-focused interventions, such as trained peer counseling and frequent contact through text and social media, should be used to improve outcomes for youth with HIV.

“A new Kaiser Permanente primary care model utilizes pharmacists and pharmacy technicians.”

Primary Care Model Leveraging Pharmacists Can Curb Health Costs

A new Kaiser Permanente primary care model, detailed in a recent issue of Harvard Business Review, utilizes pharmacists and pharmacy technicians, along with other medical staff, to save significant health care costs.

The program, designed for treating patients with multiple chronic diseases, uses technology and medical staff to provide expanded support to primary care physicians, allowing pharmacists to access laboratory data and make many of the medication changes needed. The model is already implemented in California, Virginia, Maryland, and the District of Columbia, and “significantly reduces costs and improves the quality of care,” according to Harvard Business Review.
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alk into a pharmacy in 2030 and there’s a good chance you’ll see a pharmacist. And there’s a good chance the pharmacist will have little or nothing to do with dispensing. “We will have less to do in the future with actual medications,” predicted Michael Rea, PharmD, founder and chief executive officer of Rx Savings Solutions, a medication therapy management firm in Kansas City. “Pharmacists might still be responsible for dispensing, but they won’t be counting byives and maybe not looking at pill vials. Automation, robots, software can probably do the job faster and more accurately when it comes to dispensing. Pharmacists will be adding value and improving health outcomes in other ways.”

State practice acts still make pharmacists responsible for safe and accurate dispensing, but economics are squeezing pharmacists out of the process. Amazon bought PillPack in 2018 and is seeking pharmacy trademarks in more than a dozen countries. The company also advised patients in 2019 that it would be adding Amazon Pharmacy to packaging.

However, Amazon isn’t alone in squeezing prescription profit margins. Other e-pharmacy startups are also offering fast, low-cost delivery of Rx medications as payers and pharmacy benefit managers (PBMs) continue to trim already-low product reimbursement and pharmacy profit margins.

“Dispensing is dying,” said Becky Winslow, PharmD, senior pharmacoeconomics specialist, Medical Affairs, Admera Health. “I was a pharmacy manager for Walmart 21 years ago and started plotting my way out within 2 years. I could see the business model just wasn’t sustainable.”

Changing Business Models
Traditional dispensing will be even less sustainable in 2030, Rea predicted. Independent pharmacies have long offered home delivery. Facing increasing pressure from Amazon and other online sellers as well as independents, CVS, Walgreens, and other chains are rolling out their own delivery programs.

But growing home delivery means shrinking foot traffic, Rea noted. That means lower retail prescription volume and lower non-Rx sales on a per-store basis. Major chains have been closing lower performing stores for years, increasing pressure on pharmacist employment.

"Dispensing is dying," said Becky Winslow, PharmD, senior pharmacoeconomics specialist, Medical Affairs, Admera Health. “I was a pharmacy manager for Walmart 21 years ago and started plotting my way out within 2 years. I could see the business model just wasn’t sustainable.”
On the flip side, patients, like other consumers, want convenience. That means more care at home, at work, and in community locations.

"Pharmacy has the potential to be one of the points of access," said Lucinda Maine, PhD, RPh, executive vice president and chief executive officer of the American Association of Colleges of Pharmacy.

Pharmacists continue to be the most trusted and most accessible health care providers. Patients visit a pharmacy an average of 35 times per year compared with just 4 visits to see medical providers, according to Jennifer Zilka, group vice president of Good Neighbor Pharmacy Field Programs and Services. New business models play to those 2 strengths.

“We are seeing a move from financial models based on volume to models that are clinically focused on quality, keeping people healthy and out of the hospital,” Zilka said. “The goal is better clinical outcomes and pharmacists are poised to play an important role on the health care team to improve outcomes.”

Focus on outcomes is already a reality in health system settings, she continued. Most systems currently have pharmacists on the floors monitoring interactions, evaluating therapy, adjusting medications, and working with the rest of the health care team to optimize outcomes. Retail pharmacists have an opportunity to play a similar role in the community.

“I see more point-of-care testing in 2030 in community pharmacy and prescribing on the spot,” she predicted. “More immunizations, more compounding. The next 10 years is transforming practice from dispensing a product to providing a flexible, high-touch, personalized service experience with better clinical outcomes.”

Reimbursement is in flux. Payment from public and private payers is moving toward value-based, but fee-for-service still dominates some sectors, including pharmacy.

“Changing payment models are conducing to cobbled together the resources to support a pharmacist,” explained Anne Burns, RPh, vice president of professional affairs for the American Pharmacists Association. “Practices that have moved to value-based have the incentive to bring providers to the table who can impact their quality metrics and outcomes. There is an increasing appetite for the role that pharmacists can play. The evidence is building that pharmacists can contribute to outcomes.”

The key to pharmacy success in 2030 is focusing on the specialized knowledge and training of pharmacists. Every provider in health care has a niche. Physicians are trained to diagnose, nurses to support, and physical therapists to improve physical function. Pharmacists are the providers trained in medication science.

Not understanding the science of drug delivery, activity, and interactions is an important reason so many patients get the wrong drug at the wrong time, said Calvin Knowlton, PhD, founder, chair, and chief executive officer of health care informatics provider Tabula Rasa Healthcare. This is also 1 reason adverse drug events (ADEs) have become the third leading cause of death in the United States after heart disease and cancer.

“The most common therapeutic intervention in the world is pharmacotherapy,” Knowlton said. “For every dollar we spend on prescription medication, we spend more than another dollar trying to address problems caused by the medications. Pharmacists can change that, pharmacists are being paid to change that. Don’t worry about prescriptions—let Amazon or 1 of their competitors do it.”

Pharmacist or Pharmacy?

Patients typically fall into 1 of 2 categories, Zilka said. They need a familiar prescription refilled with no changes, no questions, no complications, and no worries. They need a channel to get their medication as conveniently and as cheaply as possible. They need a pharmacy.

Or, they need personal attention due to a new prescription that requires counseling or multiple medications with the potential for interactions and ADEs. They need someone who can walk them through the quirks of 3 different asthma inhalers, someone who help them afford their medications, and someone who understands the underlying science of all of the factors that play into drug activity. They need a pharmacist.

"Payers are realizing that when pharmacists are involved with patients, they can have a significant impact on lowering the total cost of care," said Kurt
The Future of Pharmacy

Increasingly, payers are going to want to work with pharmacists and pharmacies that are achieving good patient outcomes.

- KURT PROCTOR

Proctor, PhD, RPh, senior vice president of strategic initiatives for the National Community Pharmacists Association (NCPA) and president of the NCPA Innovation Center. “Increasingly, payers are going to want to work with pharmacists and pharmacies that are achieving good patient outcomes.”

Dispensing won’t go away, Proctor predicted, but pharmacies that can demonstrate improved outcomes will earn the privilege of dispensing as well as providing services. And patients will be incentivized to use specific pharmacies that show positive results.

Look for technology to update familiar processes such as drug utilization review (DUR). The basic DUR technology is nearly 50 years old and scans for interactions between 2 agents. That’s a problem when approximately half of older adults are taking 5 or more medications.

One-to-one DUR embedded in electronic health records, pharmacies, PBMs, and other systems is archaic, Knowlton said.

Tabula Rasa is currently testing MedWise, a simultaneous, multi-drug DUR incorporating pharmacodynamics, pharmacokinetics, pharmacogenomics, and chronopharmacology in multiple Part D populations. Clinical pharmacists provide personalized follow-up with patients and prescribers with specific recommendations for deprescribing, substitutions, and timing changes to improve outcomes.

In 6 months, medication use decreased about 27%, hospitalizations by 43%, and emergency room visits by 20%. Per patient per year savings were approximately $4,000 and the total return on investment was 13:1.

Science and reimbursement are the only limits on pharmacist roles in 2030, Proctor said. As pharmacotherapeutic science advances, so do potential niches for pharmacists.

“We are already seeing point-of-care testing,” Maine said. “Pharmacogenomic analyses are beginning to be applied to drug selection and dosing. There is going to be a lot more health information technology that impacts diagnosis, therapeutic, and patient management. Pharmacists can help solve our medication problems—if we let them.”

LOOKING AHEAD AT PHARMACOGENOMICS, NUTRIGENOMICS

Pharmacogenomics and nutrigenomics are early contenders for the hottest new area in pharmacy. Neither is board-certified, but the American Society of Health-System Pharmacists launched its first pharmacogenomics certificate program in 2018.

“Pharmacists need to take a very involved pharmacogenomics role with both patients and providers,” said Jaclyn Boyle, PharmD, MS, PhD, associate professor of pharmacy practice at Northeast Ohio Medi-

cal University. “Once we know how a variant in an individual’s genome affects the way they can process a particular medication, there are many implications for the selection, effectiveness, and safety of therapies and interactions. Pharmacogenomics data can help inform decision about whether a patient should try a medication, stay on it, whether a given med is going to either positively or negatively impact the patient.”

Boyle is chief executive officer of Synerji, a startup turning pharmacogenomics and nutrigenomics into everyday tools for pharmacists.

Think clopidogrel. “Plavix (clopidogrel, Bristol-Myers Squibb) helped put pharmacogenomics on the map,” said Winslow. “But the bulk of pharmacogenomics research is in oncology, psychiatry and most recently, pain. Only about 50% of women who are getting chemotherapy for breast cancer can even benefit. They don’t need chemotherapy, they need hormone receptor medications, but only genetic testing can show that. Medication selection and counseling based on genomic data is a huge unmet need.” Winslow founded inGENErous RX to commercialize pharmacogenomics. As the list of cardiovascular, oncology, and other specialty medications with known pharmacogenomic interactions grows, more and more payers are covering genomic testing. Nutrigenomics is close behind.

“Nutrigenomics counseling could play a big role in disease states where nutrition plays a role, which is most of our chronic diseases,” Boyle said. “Nutrition impacts the development and progression of diabetes, cardiovascular disease, kidney disease, irritable bowel syndrome and other GI conditions, and so much more.”

Genetic variants can play a huge role in response to both medications and nutrition.

“We know that metformin depletes vitamin B12 and processing B12 poorly is a compounding factor,” she said. “Nutrigenomics data can help us spot that potential problem to improve the patient’s medication outcomes. Once we start showing improvements in outcomes, payers are negotiating reimbursement.”

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We all check in with our smartphones more than a few times throughout the day. Whether we’re responding to texts or scrolling through our social feeds, it can be difficult to refrain from the distraction of our mobile devices. But what if there was a way to make your phone actually useful at work?

From drug information to patient education, these apps can help you be better at everything that you do.

1. **Epocrates**
   Epocrates, a point-of-care medical application, is widely regarded as a useful tool for pharmacists. The app itself provides clinical reference information on drugs and has a variety of features such as a drug interaction checker, pill identifier, and drug coverage information for insurance plans. Most of the app’s offerings are free of charge, although additional features may be included for a monthly fee. This includes medicine monographs, peer-reviewed disease content from the BMJ, and labs, ICD-10 codes, and more.

2. **Pocket Pharmacist**
   The Pocket Pharmacist app provides pharmacist-curated drug information that can be useful if you need to look something up quickly. According to the company’s description, it “feels like you’re talking to a live pharmacist versus reading through an encyclopedia.” The tool is good for drug information, searching for drug interactions, and testing your own knowledge through medication quizzes.

3. **CDC Vaccine Schedules**
   Here’s a way to have the latest recommended immunization schedules at your fingertips. The CDC’s Vaccine Schedules app visually mimics the printed schedules which are reviewed and published annually, including the most current version of the schedules for children and adolescents, catch-up schedule for children, adult schedule (as recommended by age group and medical conditions), and an adult contraindications and precautions table. Any changes in the schedule are released through app updates.

4. **Drugs.com Medication Guide**
   Drugs.com offers a comprehensive app filled with information that allows you to check drug interactions, identify pills, and create custom lists and reports. The app also offers in-depth consumer information, FDA alerts, and a complete A-to-Z database of drug information.

5. **Merck Manual Professional**
   The Merck Manual has been the go-to source for medical knowledge, and now you can put all that in your pocket—without having to lug around a 20-pound book and flip endlessly through thousands of pages. The app contains thousands of regularly-updated articles, drug reference information, illustrations, and much more—all available for free.

6. **Lexicomp**
   In addition to drug references, this tool has unique features such as pharmacogenomics databases, IV compatibility data, patient education leaflets, drug shortage information, and the ability to reorder databases and monograph fields to customize displays. According to the company, the content is also stored directly on the device, making it feasible to quickly answer questions while on the go even if there’s no internet connection.

7. **Drugs@FDA Express**
   The FDA’s Drugs@FDA Express app is a free mobile version of the agency’s online database of information on approved drugs. Users can search and browse by drug name, active ingredient, or application number. A list of recent approvals, organized by date, can also be viewed in the ‘Last 7 Days’ Approvals’ option.
How To Turn Into A ‘Diabetes Pharmacy’

Creating a place where patients seek diabetes care and counseling

By Joan Vos MacDonald

According to the CDC, approximately 30.3 million people in the United States have diabetes. Pharmacies that offer ongoing diabetes care and counseling do more than deliver a valuable service; providing such services makes sound business sense.

“Patients need help navigating their care and managing the disease,” said Dorinda Martin, PharmD, RPh, FACA, FASAP. “Diabetic patients fill more prescriptions and visit the pharmacy more often than most of our other patients. The more services and products we offer, the more patients we will see. It’s the ‘build it and they will come’ story. Offering individualized patient care and not just prescriptions increases patient trust, dedication and loyalty.”

One common way pharmacists help patients with diabetes is by showing them how to properly use prescribed devices. Although basic instruction in the self-monitoring of blood glucose levels is the set-up and demonstration of the device, pharmacists can use the opportunity to present information on glycemic goals. What should glucose levels be during fasting, before meals, after meals, and bedtime? What are the signs/symptoms/treatment of high and low glucose values and how often should I test?

Answering the simplest questions can be a game changer.

“Interestingly, ‘How often should I test my blood glucose?’ is repeatedly asked—patients often state they have never been told how often or when to check glucose levels so this is an excellent opportunity for pharmacists,” said Jennifer Smith, PharmD, BCACP, BCADM, CDE.

“My one question I always ask takes 2 seconds. ‘Where do you inject your insulin?’ You would be amazed at the responses received (ie calf, breast, back, forearm). This becomes the easiest diabetes education moment that will profoundly impact absorption that takes less than 10 seconds to complete. Even the busiest pharmacist can spare 10 seconds.”

Monitoring medication use and adherence may be a more time-consuming task, but it’s something pharmacists are uniquely positioned to do. Pharmacists can recognize when medications are not optimized, if another medication is recommended for comorbid diseases, but not prescribed, and note any adverse or intolerable effects.

Ideally, counseling on the importance of medication adherence, plus the risks of the newly-diagnosed disease, should begin when a patient first shows up at the pharmacy with a new prescription for diabetes.

“If they don’t have time at that moment of POS, then promise to call them the next day and outline what services the pharmacy offers, such as 1-on-1 diabetic counseling,” Martin said. “Create a summary and a template sheet for each pharmacist to create a plan for each of these patients, then place in ticker to ensure a follow-up call to monitor the patient every few months. This follow-up could include taking their weight and blood pressure as well as A1c and checking on their immunization records.”

Whether diabetes care and counseling happens in an independent pharmacy or at a nationwide pharmacy chain, systems that monitor patient adherence are an essential tool. At Walgreens pharmacies, pharmacists use a program with predictive analytics to identify patients most likely to become nonadherent to their maintenance medications, including those with diabetes, then provide personalized recommendations.

“By providing patient specific solutions to help them effectively manage their chronic condition, lifestyle

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modifications and medication regimen, diabetes patients can be empowered to meet their health goals,” said Alexandra Brodus, PharmD, director, Patient Outcomes Performance for Walgreens.

Prominently displaying diabetes products and services in the pharmacy is a good way to let customers know what you offer, but pharmacists can also help spread the word in the community.

“Outside of our stores, it’s important that pharmacists are participating in local community events and organizations to raise awareness of the care and services they can provide,” said Brodus. “Our pharmacists participate in community outreach programs. As part of these, we offer presentations on diabetes care and solutions.”

Walgreens recently launched the “Missing Therapy–Statin Use” program to help identify patients with diabetes who are not currently taking a statin and provide education and physician outreach around the heart health benefits of statins.

“The American Diabetes Association (ADA) recommends that diabetes patients over the age of 40 include a statin as part of their drug therapy to lower their risk for heart disease,” Brodus said. “Yet, many patients with diabetes have never been offered a statin.”

CVS launched its Transform Diabetes Care program in 2017 and expanded it in 2019 to focus on prevention and early identification of diabetes, as well as hypertension, a common comorbidity of diabetes. The program helps pharmacy benefit manager (PBM) members control their diabetes through a combination of personalized support and coaching focused on improving medication adherence and better control of HbA1c.

“More than 50% of members with uncontrolled diabetes who enrolled in the program have moved to a controlled status and, on average, members have improved HbA1c by 1.2 percentage points,” said Peter Simmons, RPh, vice president of Chronic Care Optimization at CVS.

Personalized coaching and support for healthy lifestyle behaviors can be delivered at the pharmacy or by phone. Members can also receive diabetes monitoring at MinuteClinic locations at no out-of-pocket cost, including A1C checks.

“In addition, members are offered a connected glucometer, which shares their blood glucose levels with a pharmacist-led team via a health cloud, enabling the team to identify potential issues and intervene with 1-on-1 coaching,” said Simmons.

Patients have the option of not only getting refill reminders by text but can also text their requests for refills.

“Patients commonly convey that they’re frustrated, and that they find their diabetes to be challenging, inconvenient, and difficult to manage,” Simmons said. “Our expanded program is designed to make it easier for a broader range of patients to keep their diabetes under control, prevent complications, and manage related conditions like high blood pressure in a coordinated way.”

As well as counseling patients already diagnosed with diabetes, pharmacists can screen those who may be at risk.

“Per the American Diabetes Association (ADA) Standards of Medical Care in Diabetes, an informal assessment of risk factors for [type 2 diabetes mellitus] or the use of a validated tool should be used in asymptomatic adults,” Smith said. “The ADA Risk Test is readily available on page S21 of the 2020 guideline and is a good tool for pharmacists to review with patients.”

Screenings can provide an opportunity for pharmacists to suggest preventive steps that can reduce an individual’s risk, such as healthy eating habits and exercise.

“Often, pharmacists feel they need to be a Certified Diabetes Educator (CDE) in order to effectively provide diabetes education to patients, which is inaccurate,” Smith said.

Many health care professionals hold the title of diabetes educator while working toward the hours of hands-on education required before the CDE exam.

“Ideally, pharmacists should have basic knowledge of counseling tips for available diabetes medications, basic diet information for patients living with diabetes, an understanding of guideline recommendations for glycemic goals and pharmacologic treatment, and the ability to recognize glucose patterns from home monitoring,” Smith said. “These are all covered in the APhA Diabetes Certificate Training Program which offers online modules for learning at a self-set pace and a hands-on live seminar for application of the material covered in the modules.”

As pharmacy schools offer more diabetes management education, newer graduates may need less additional training, but there are multiple options should training be needed.

“I wanted to be sure my pharmacists were knowledgeable,” said Martín of her Texas-based pharmacy Martin’s Wellness Dripping Springs Pharmacy. “So I sent 4 of us to a certified diabetes education class (20 hours of CE) at a local college of pharmacy. This allowed a confidence level that benefited the pharmacists and our patients.”

For references, visit DrugTopics.com

**Diabetes / How To Turn Into A Diabetes Pharmacy**
Prepare for Allergy Season

Relieving symptoms and optimizing therapies for allergic rhinitis

By Frieda Wiley, PharmD

The advent of spring represents new life and rebirth of nature. Unfortunately for many, the budding plants come with consequences in the form of watery eyes, stuffy or runny nose, scratchy throat, and sneezing. So bothersome are these signs and symptoms of allergic rhinitis, in fact, that America spends more than $18 billion treating allergies each year, according to the American College of Allergy, Asthma, and Immunology.1

Corticosteroids are first-line therapy for seasonal allergic rhinitis in patients who are 12 years of age and older. They provide acute relief and are the most effective medications to curtail allergic complaints, according to Elizabeth Richardson, PharmD, BCPS, assistant professor of pharmacy practice at Butler University and clinical pharmacy specialist in internal medicine at Indiana University Health Methodist Hospital.

To optimize benefit and limit allergic symptoms, proper adherence to corticosteroid therapy is critical, said Gary Gross, MD, an allergist on the medical staff at Texas Health Presbyterian Hospital Dallas. Patients often expect that intranasal corticosteroids (ie, budesonide, triamcinolone, and fluticasone) will provide instant relief and become discouraged when they do not. Many patients either give up too quickly on using intranasal corticosteroids, or they stop using the medication once symptoms improve, so their complaints return.

Gross also encourages patients to begin using intranasal corticosteroids either when allergy seasons starts or a week prior.

“Patients need to be educated that antihistamines provide relief from sneezing, itching, and runny nose and that decongestants reduce congestion.”

While intranasal corticosteroids keep allergic symptoms at bay, patients have other options. Depending on their symptoms, antihistamines and decongestants can give additional or alternative relief.

However, as Gross noted, one common pitfall occurs when patients seeking relief from nasal congestion erroneously select an antihistamine instead of a decongestant.

“Some people pick the wrong medicine,” he said. “Patients need to be educated that antihistamines provide relief from sneezing, itching, and runny nose and that decongestants reduce congestion.”

Another important differentiating point between antihistamines and decongestants is that decongestants elevate the blood pressure, whereas antihistamines do not.

Pharmacists should consider the adverse effect profile when recommending antihistamines. Although effective, the first-generation antihistamine diphenhydramine has strong sedating effects. For this reason, as well as the overall lower adverse effect profile, Richardson recommends second-generation antihistamines. Her top choices for second-generation antihistamines are loratadine and cetirizine because they tend to be cheaper than their cousin, fexofenadine.

For patients who require a decongestant, Gross recommends pseudoephedrine, cautioning that its stimulating effects may interfere with sleep if taken late in the day.

He also encourages patients to rinse their nares daily with saline solution.

“People like it because it is natural and can be used often,” he said.

On a final note, pharmacists should also advise patients against using allergy medicine when they have conditions where the signs and symptoms are not allergy-related. For example, individuals with a cold sometimes try to treat their illness with antihistamines. The same holds true for patients who have dry eye. Some of these patients tend to use allergy eye drops, which Gross cautions is the wrong use for the medicine. They may resolve the redness, but they do little to moisturize the eyes.

For references, visit drugtopics.com
What Pharmacists Should Know About Multiple Sclerosis

By Jennifer Gershman, PharmD, CPh

Approximately 1 million individuals are living with multiple sclerosis (MS) in the United States, according to the National MS Society. MS is caused by the immune system attacking the protective sheath (myelin) that covers nerve fibers and can result in a wide range of symptoms such as the inability to walk. Most patients have a relapsing-remitting disease course, which involves periods of new symptoms or relapses that occur over days or weeks and usually improves partially or completely. There is no cure for MS, so treatment involves therapies that improve recovery from attacks, slow disease progression, and manage symptoms.

Treatment Options

Treatments for MS include pharmacotherapy and physical therapy. Corticosteroids can help to treat MS attacks by reducing nerve inflammation. Adverse effects (AEs) include increased blood pressure and blood glucose, mood changes, and fluid retention. The American Academy of Neurology (AAN) recommends a careful evaluation of the risks/benefits of disease-modifying therapies (DMTs). The DMTs can help to slow the disease process and assist with keeping the condition stable by decreasing the number of new lesions that can form, preventing existing ones from becoming larger, and decreasing the number of relapses.

Treatment options include injectable medications, oral treatments, and infusions. Beta interferons, such as interferon beta-1a (Avonex), are injectable treatments, and common AEs include flu-like symptoms and pain at the injection site. Glatiramer acetate (Copaxone, Glatopa) is a subcutaneous injection, and adverse effects may include injection site reactions.

Three new oral medications were approved for MS in 2019: cladribine (Mavenclad), siponimod (Mayzent), and diroximel fumarate (Vumerity). The dose of cladribine is a cumulative dosage of 3.5 mg/kg orally divided into 2 yearly treatment courses, and the drug carries a Boxed Warning for an increased risk of cancer and fetal harm. Siponimod dosing is determined by genotype testing and is either 1 mg or 2 mg orally once daily. AEs may include headache, bradycardia, increased blood pressure, and increases in liver function tests. The starting dose of diroximel fumarate is 231 mg twice a day orally for 7 days followed by a maintenance dose of 462 mg (two 231 mg capsules) twice per day. Diroximel fumarate can cause liver problems and a rare brain infection known as progressive multifocal leukoencephalopathy, which has also been reported in patients taking a similar drug called dimethyl fumarate (Tecfidera). Evidence suggests that diroximel fumarate may cause less gastrointestinal AEs than dimethyl fumarate.

Individuals with MS receiving immunosuppressive therapies are at a higher risk of developing vaccine-preventable infections. Pharmacists should ensure that patients are up-to-date on their immunizations and recommend annual influenza vaccination. The AAN recommends that patients needing live vaccines receive them at least 4 to 6 weeks before initiating treatment with immunosuppressive medications. Individuals who are receiving immunosuppressive therapies or have recently discontinued them should not receive live vaccines unless the risk of infection is high.

Pipeline Drugs on the Horizon

Celgene has submitted a New Drug Application (NDA) for ozanimod, an oral sphingosine 1-phosphate receptor modulator, with an anticipated approval date of March 25, 2020. Ponesimod is also an investigational drug that is being studied by Janssen for relapsing MS.

For references, visit DrugTopics.com
Growing Your Business With Supplements  

By Karen Appold

Americans are desperate to be well. Being well, however, is not the business model of modern medicine, according to Kathy Campbell, PharmD, clinical community pharmacist and CEO/owner of Dr Kathy Health, LLC, and Medicap Pharmacy in Owasso, Oklahoma. The American health care system is structured to respond to a patient’s diagnosis, not prevent disease.

The $40 billion supplement industry, which includes vitamins and nutraceuticals, represents Americans’ willingness to spend money to be healthy. “Pharmacists are perfectly positioned and trained to understand the chemistry of supplements and foods, and as well as drugs and diseases,” Campbell said. “They can assist customers by recommending appropriate supplements. Sales of these products can also benefit a pharmacy’s bottom line.”

Bowe Craine, PharmD, co-owner and pharmacist in charge at Okie’s Pharmacy II Inc., in Blaine, Tennessee, agreed and said that pharmacists should be at the forefront of not only selling supplements, but that they should also educate patients on OTC products that may not be FDA approved.

Getting Started
When looking to grow business with supplement sales, pharmacists should first educate themselves “Research the most common products in various categories, and then analyze which ones fit your community’s needs,” Craine said. For example, if you have a large patient population with inflammatory conditions, such as irritable bowel disease or arthritis, then you should start with products like turmeric, fish oil, or cannabidiol (CBD) oil.

“Get out from behind the counter and talk to customers,” Craine said. “Ask how they feel about their current therapies and if they’re sufficient. Be confident in your ability to make recommendations about products that can improve quality of life. Not only will you increase your sales and profit margins, but you will also create loyal customers and build trusting relationships.”

Campbell recommended attending an 8-hour continuing education course from the National Community Pharmacists Association and Dr Kathy Health, Creating Health-Pharmacist-led Lifestyle and Weight Management, which teaches supplementation basics and Foundational training in assisting patients with health.

When researching supplements, Craine uses UpToDate, PubMed, or the Dietary Supplements Labels Database to study their safety, efficacy, and various uses.

National Center for Complementary and Integrative Health’s website is also recommended to get a better understanding of the usefulness and safety of supplements with evidenced-based research, advises Dipan B. Ray, MPharm, MS, PhD, RPh, senior director of experiential education at Touro College of Pharmacy in New York, New York.

Nina Chhabra, PharmD, a natural medicines specialist at Northwell Health/Vivo Health Pharmacy in New Hyde Park, New York, subscribes to reputable databases, such as the Natural Medicine Database, which provides detailed information regarding supplements like their level of effectiveness, safety information, dosing information, and possible drug interactions. ConsumerLabs.com provides third-party testing results. The National Institute of Health’s website shows if any clinical trials were conducted to support

Total Users’ Reasons for Taking Dietary Supplements

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>27%</td>
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<tr>
<td>25%</td>
<td>Fill nutrient gaps in diet</td>
</tr>
<tr>
<td>24%</td>
<td>Health aging</td>
</tr>
</tbody>
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Source: Council for Responsible Nutrition’s 2019 CRN Consumer Survey on Dietary Supplements
a particular product’s usage, she said.

**Popular Products**

By far, the most popular supplement Craine sells are multivitamins. “Consumers take them mainly to avoid vitamin deficiencies which can lead to problems such as osteoporosis, muscle cramps, and fatigue,” he said.

Hemp-derived CBD topped Chhabra’s list in 2019. Patients use this product to help manage anxiety and stress, for insomnia or to support sleep, and for different types of pain related to fibromyalgia, headaches and migraines, and muscle and joint pain.

Vitamin D is the most popular supplement currently used. It helps the body absorb calcium in order to increase bone density and therefore reduces the risk of developing osteoporosis, especially in women and the elderly, he said.

**Adverse Drug Reactions**

In addition to serving as a resource on which supplements to take, pharmacists should make customers aware of possible adverse drug reactions.

A general myth is that most supplements are safe because they’re derived from natural sources. “The truth is that a majority of herbal supplements interact with other drugs and can have significant adverse effects,” Ray said.

For example, Chhabra noted that turmeric, curcumin, and fish oil supplements can thin blood. If a patient takes a blood-thinning agent such as aspirin or warfarin, she warns them to stop taking these supplements before surgery or any medical procedure that could affect their clotting time.

Chamomile, often used as a sleep aid, interacts with birth control, Craine pointed out. Ginger, which prevents nausea and vomiting, can lower blood sugar and interact with blood thinners if high doses are taken. Yohimbe may aid with erectile dysfunction, but it can raise blood pressure and heart rate and cause tremors.

**Counseling Patients**

Consumers should understand the importance of selecting the most appropriate products depending on their medical histories and current medication use. “Before using any such products, patients should share their current medications and over-the-counter products with their physicians and pharmacists so they can counsel them about any potential risks and benefits,” Ray said. “I encourage patients to report any side effects to physicians or pharmacists immediately.”

Because the kidneys and liver break down supplements just as they do prescription drugs, Chhabra asks customers if they have any issues with these products. “Conversely, the most frequently asked questions Chhabra gets from patients is if a product is safe and if it works. “I emphasize that safety is our primary concern, however it is hard to find robust clinical evidence about efficacy,” Chhabra said. “This is simply because large trials that can show this are rarely performed. Unlike prescription drugs, supplements are considered safe unless proven otherwise.”

Currently, Chhabra also receives many questions about hemp-based CBD products. “Although CBD appears to be safe, it is relatively new and we’re still learning its exact uses,” she said. “I recommend patients start taking low doses and slowly increase the dosage every 2 to 3 days until they feel an effect. But I caution them to only use products that provide third-party testing results, which can help ensure it’s a quality product and reveal its CBD content as well as any contaminants such as heavy metals, pesticides, and bacterial growth.”

SUPPLEMENTS, VITAMINS, AND NUTRACEUTICALS

What’s the Difference?

The best way to describe the differences between vitamins, supplements, and nutraceuticals is to consider supplements as the main category that these agents fall into.

Nutraceutical products are generally derived from food sources intended to be used for health benefits, whereas vitamins are organic compounds that are needed from external sources, such as food, because the body can’t make them, explained Nina Chhabra, PharmD. “If someone can’t obtain enough of a necessary vitamin from a food source alone, they may use a supplement that contains that specific vitamin,” Chhabra said. “Vitamins are essential for bodily functions, whereas nutraceuticals are used to supplement the diet and are typically food or food sources and are used for a specific health benefit.”

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Consumers should understand the importance of selecting the most appropriate products depending on their medical histories and current medication use. “Before using any such products, patients should share their current medications and over-the-counter products with their physicians and pharmacists so they can counsel them about any potential risks and benefits,” Ray said. “I encourage patients to report any side effects to physicians or pharmacists immediately.”

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The most frequently asked question consumers ask Ray is, “How much should I take?” He pointed out that all vitamins need to meet a certain Recommended Daily Allowance (RDA) as stated on the label to achieve desired benefits.

For references, visit DrugTopics.com
Making A Career Pivot
Pharmacy managers and educators offer career advice

By Keith Loria

Obtaining a PharmD has such broad value when it comes to career offerings, and those offerings can best align with not only one’s personal strengths, but professional goals. Sure, you can look to practice as a pharmacist in the community setting or within the hospital setting—where the majority of jobs still reside—but there are non-traditional roles that pharmacists play as well.

“Serving in the long-term care market, the specialty pharmacy market, or even the ambulatory care setting, pharmacists can use their clinical expertise to directly impact the patient’s utilization and response to taking medications,” said Jonathan Ogurchak, PharmD, CSP, founder and CEO of STACK, a compliance management software company for pharmacists. “Beyond that, pharmacists can be looked upon as educators, frequently being hired as medical science liaisons within the pharmaceutical industry and tasked with teaching providers about disease processes and the medications used to treat them.”

Informing Students
Pharmacy schools are tasked with a huge responsibility—not only training pharmacists to understand the complexities of disease states and the drugs to manage, but also with educating about career opportunities.

“The experiential education component of the curriculum plays a huge part in understanding what types of roles might be available, since it’s often one of the closest steps to direct practice that student pharmacists would have prior to graduation,” Ogurchak said.

Pharmacy students regularly do rotations during their last year of schooling, which places them in different industries and shows them how different segments of pharmacy operate. But just because they decide to go in one direction initially does not mean they are stuck in that area for their entire career.

Jeannie K Lee, PharmD, BCPS, BCGP, FASHP, associate professor for pharmacy practice and science at the University of Arizona College of Pharmacy, said that often students know about community pharmacy work, but not much more.

“That’s why, at the University of Arizona College of Pharmacy, one of the courses students participate in their first semester is Pharmacy Practice, where students take a survey of their interest areas and learn how to explore and pursue those fields through resources that have been gathered for them.

“At the same time, practitioners from various pharmacy careers come into class to present their journey and engage students in a question and answer session,” Lee said. “Our students are surveyed each year to help them explore as many career paths in pharmacy as they wish.”

Tips for the Established Pharmacist
It’s not unusual for someone in the pharmacy field to want to find something new and pivot to a different career path in pharmacy, and it’s not as hard to do as some may think.

Lee noted that the best way to start a possible switch is to first explore the field of pharmacy they are passionate about and identify details—training needed, procedures, types of patients, niche opportunity, collaborators, settings, salary, benefits, etc.

“For each possible position, they may want to create a pro and con list to think about the choice deeply and to help with decision making,” she said. “It will help tremendously to talk with a pharmacist who is currently in the position to learn about their path and other they know of.”

Nonye Uddoh, PharmD, BCACP, clinical pharmacist at CHC Health, pivoted from retail to managed care 5 years ago by gaining additional certifications and experience outside of her 9-to-5 schedule, and by networking with other pharmacists. She believes others can make a smooth transition.

“What I’m noticing in the field is the focus on developing yourself with certifications and/or residency, consider gaining more than 1 state license, connect with your colleagues and add value as much as possible,” Uddoh said.
The elective components of those programs offer views into different career opportunities that are experienced for a few weeks at a time, and allowing for exposure for more non-traditional career paths.

**Resources Abound**

For students or current pharmacists looking to learn about the many opportunities, there are plenty of easy ways to discover these on the web. Thankfully, students can learn about pharmacy career choices through the American Pharmacist Association (APhA) and many pharmacy programs encourage students to explore all options.

Pharmacyforme is geared toward students thinking about pharmacy as a career; the APhA site is for students and professionals exploring different areas of pharmacy. Pharmacists can also review the APhA career center information.

"A career as a pharmacist is so much more than 1 job—it’s a combination of all of one’s experiences from the time they enter school through the time they retire," Ogurchak said. "Finding ways to utilize each one of those experiences across the course of a career helps one to practice as a better, well-rounded practitioner."

It’s also important to keep in mind that pharmacy is a very small world. "It is like ’6 Degrees of Kevin Bacon.’ Someone is bound to know someone, who knows someone, who you’ve worked with," Dhing said. "Being an engaged, professional employee who helps your organization reach its goals is always valued. When you help your organization reach their goals, you’re more likely to develop a positive reputation and reach your own personal goals."

Conrad Dhing, PhD, assistant dean of student academic affairs at Husson University’s School of Pharmacy, noted that many hospitals and pharmacy chains have internal career development programs to help someone learn of other opportunities.

Ogurchak added that demonstrating an understanding of the profession, based on practice experience, carries a huge weight when looking to shift career opportunities.

"Often times, the ability to relate prior situations into more broad terms can highlight your ability to perform in new scenarios—especially if you’re looking to move into a new setting for practice,” he said. "Demonstrating a desire to learn is also critical—either through highlighting continuing education that you’ve completed in a particular practice area, additional trainings, or certifications that you may have achieved as well."

**Challenges of Making a Switch**

Lee believes a silo-thinking approach to different areas of pharmacy might make it more challenging, where people think that they are “stuck” in an area of pharmacy they started with. But the knowledge and skill sets are transferable.

For example, over a 20-year career in pharmacy, Lee has worked in community pharmacy (as a student); ambulatory care clinics in internal medicine/primary care, cardiology and geriatrics; home-based primary care and interprofessional home visits; hospital work in pain management and rehab, adult acute care and critical care; and academia, research, and administration.

Those wanting a similar career path can achieve it.

“Think engagement is key—seek out pharmacists in different areas of pharmacy to receive mentorship and guidance. Pharmacists are by and large kind and generous people, and you can benefit from their experiences and wisdom,” Lee said. "Also, advocate for the pharmacy profession so that our paths continue to enlarge and not become stagnant or narrow."

Kelley D. Carlstrom, PharmD, BCOP, a clinical oncology pharmacist, is contacted often by pharmacists who want to pivot into oncology.

"It is rare to be handed an opportunity in oncology with no prior experience, although I’ve talked to a few pharmacists that were in the right place at the right time and recognized the opportunity," she said. "So, keep your eyes/ears open for any opportunity to get exposure to oncology drugs, patients, or systems in any capacity."

For example, if your site has a cancer center, she recommended volunteering to cross-train.

“Most pharmacists shy away from chemotherapy so that provides an opportunity for you,” Carlstrom said. "If you work in retail, spend extra time with patients that are filling supportive care medications; you may even dispense some oral chemotherapy."

Furthermore, if your site doesn’t have a cancer or infusion center, Carlstrom suggested looking for one local to you that does and follow them on LinkedIn, and connect with others that work there.

“Build and grow your professional network—this is said a lot these days but can’t be overstated," she said. "Don’t blindly grow your network, but be proactive by interacting with people regularly. I highly recommend LinkedIn but networking in person at local events is very impactful. There is also a great online community at the Pharmacist’s Slack.”

**Making a Switch**

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Why Did You Become A Pharmacist?

By Karen Berger, PharmD

We asked pharmacists from various settings around the country: “Why did you become a pharmacist, and what keeps you motivated?” Their answers are refreshing and motivating, and a reminder of why we all chose pharmacy.

Larry Riggi, PharmD, Pharmacy Manager
Walgreens, Spencerport, NY

“I started a part-time job at a retail pharmacy and my pharmacy manager’s compassion and enthusiasm inspired me to become a pharmacist.”

Laura Dee, PharmD
Clinical Pharmacist
Crusader Community Health, Rockford, IL

“I started a part-time job at a retail pharmacy and my pharmacy manager’s compassion and enthusiasm inspired me to become a pharmacist.

As an ambulatory care pharmacist, my coworkers and my patients keep me inspired. I manage a hepatitis C clinic, and just hearing my patients’ stories of all the obstacles they’ve overcome, I’m honored that they entrust their medical care to myself and my team.”

Elaine K. Richer, RPh
CEO MyCureAll
Fair Lawn, NJ

“I always knew that I wanted to work in the medical field, and as pharmacy school was shorter than medical school, it was a no brainer.

As a newly licensed pharmacist, I loved working in a retail setting, interacting with people, helping with their questions, advising on interactions with food or medicine. It was a very ful-
Why Did You Become A Pharmacist

As the years passed, and I had my daughter, I also realized that working as a pharmacist was a great job for a female because I was able to design my schedule around my family’s needs. Pharmacy as a profession is very versatile—you can do research, or work in a hospital, industry, or retail. You are also learning something new every day—as our society evolves, so does our profession. When I started out as a pharmacist, I would never imagine vaccinating a patient or administering Narcan, but alas, that is what pharmacists are doing now. And I really enjoy it.

Now that I am in the middle of my career and I decided to completely shift my focus and work in a med/tech start up world, everything I’ve learned as a pharmacist is here to support me, and my knowledge leads the way to new and exciting opportunities.

**Arun Tandon, RPh**
Advanced Health Pharmacy
Portage, Michigan

“I became a pharmacist as I was very much interested in human health.

What keeps me going is the ability to understand health at a much deeper level and translating it to my patients. Seeing them healthier and happier drives my passion.”

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**Gunda Siska, PharmD**
Presbyterian Hospital, Albuquerque, New Mexico

“Even as a kid, I always knew I would work in a hospital. I went to LPN (licensed practical nurse) nursing school concurrently while in high school. Then I automatically went to college to pursue an RN degree, but at the last minute, I decided to pursue pharmacy school. I did retail and mail order work right out of pharmacy school, but felt restless until I got a hospital job. It thrills me to be involved in acute and critical care. I often think of my time as retail pharmacist, and now I write pharmaceutical articles to pass on the knowledge that I acquire in the hospital setting to the retail pharmacists. I think it takes a village to keep the general public safe, and the retail pharmacists are the most accessible. They are on the front lines and I admire their contributions. I want to support them the best I can. I think making the world a healthier place is my destiny and life mission.”

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**Andrea Levin, PharmD, BCACP**
Assistant Professor, Department of Pharmacy Practice
Nova Southeastern University College of Pharmacy

“I became a pharmacist because of my love and passion for medicine paired with the opportunity to make an impact in patient care. Pairing this with my love of teaching made being a pharmacist faculty the perfect path for me. This is also why I specialized in ambulatory care, as it allows for more longitudinal patient care, often times in an interprofessional setting. Ambulatory care is truly unique since you have the opportunity to interact with both other health care providers and patients equally and work as a team to provide the highest quality of care for a patient.

My motivation as a pharmacist and faculty comes from my students and patients. Seeing how proud and accomplished my students are when they make a difference in a patient’s life reminds me everyday why I love teaching. Also, seeing my patients’ HbA1c or blood pressure or some other laboratory markers either decrease or get to goal and seeing that same sense of accomplishment and knowing that their health will improve keeps me going as a pharmacist.”

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**Jennifer Gershman, PharmD, CPH**
Fort Lauderdale, Florida

“I’ve always looked up to my father, who is a pharmacist, and wanted to follow in his footsteps and make a positive impact on patient care. Educating pharmacists and patients about vaccines, new drug approvals, and hot topics in health care through writing is a true passion of mine. I enjoy helping pharmacists stay up-to-date with the ever-changing profession through drug information updates.”

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What keeps me going is the ability to understand health at a much deeper level and translating it to my patients. **Arun Tandon, RPh**
The FDA is carefully tracking shortages of personal protective equipment (PPE) as well as pharmaceutical raw materials from China due to the novel coronavirus. This is just one of the important updates about the novel coronavirus disease, also known as COVID-19.

1 FDA Response The FDA is “keenly aware that the outbreak will likely impact the medical product supply chain, including potential disruptions to supply or shortages of critical medical products in the US,” said FDA Commissioner Stephen M. Hahn, MD, in a statement. “We are not waiting for drug and device manufacturers to report shortages to us—we are proactively reaching out to manufacturers as part of our vigilant and forward-leaning approach to identifying potential disruptions or shortages.”

Although there are no vaccines, gene therapies, or blood derivatives licensed by the FDA that are manufactured in China, raw materials used in manufacturing do come from China and other locations in Southeast Asia, Hahn noted. “We are in contact with biologics manufacturers to gauge any supply concerns regarding raw materials,” Hahn said.

However, FDA has received reports of increased ordering of some essential medical devices through distributors, such as PPE (eg respirators and surgical gowns, gloves, and masks).

“If a potential shortage or disruption of medical products is identified by the FDA, we will use all available tools to react swiftly and mitigate the impact to US patients and health care professionals,” Hahn said.

2 New Research The Chinese CDC found that COVID-19 may be more contagious than the related viruses that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS), according to a new study in the Chinese Journal of Epidemiology.

The study, which is the largest of its kind, includes data from approximately 72,000 patients, CNN reported. However, the mortality rate is lower than SARS and MERS, according to the study. The Chinese CDC found a crude mortality rate of 2.3% among patients, while SARS had a mortality rate of 9.6% during the 2003 outbreak, and MERS has a case fatality of 35%.

3 Vaccine Development Sanofi Pasteur is developing a COVID-19 vaccine, in collaboration with the Biomedical Advanced Research and Development Authority (BARDA).

Sanofi will leverage previous development work on a SARS vaccine, “which may unlock a fast path forward for developing a COVID-19 vaccine,” the vaccine unit of Sanofi said in a statement. “Addressing a global health threat such as this newest coronavirus is going to take a collaborative effort, which is why we are working with BARDA to quickly advance a potential vaccine candidate,” said David Loew, global head of vaccines at Sanofi.

4 Inaccurate Treatment Claims The Center for Science in the Public Interest (CSPI) said that the FDA and the FTC should take immediate action against televangelist Jim Bakker and his organization. According to CSPI, thejimbakkershow.com claims that the Silver Solution dietary supplement products on the website can cure the coronavirus “within 12 hours.”

“There’s no evidence that the element silver prevents or treats any condition, according to authorities such as the National Center for Complimentary and Integrative Health, part of the National Institutes of Health, and the Food and Drug Administration,” CSPI said in a statement.

5 Drug Shortage Updates Healthcare Ready (formerly Rx Response) launched a separate page on its website devoted to updating the industry on shortages related to the virus, emergency preparedness information, and other news. Healthcare Ready is liaising with components of the supply chain to “better understand the current demands of supplies including pharmaceuticals and personal protective equipment (PPE),” the organization said on its website.
Addressing the ‘Glut’ of Pharmacists

Back in the late 1980s, the pharmacy profession gave so much away. We gave up reasonable dispensing fees in the name of increasing volume. We had computers; we could do more with less. We didn’t have to fill out those 3-part carbon copy claim forms with a pen, as our computers could print those out for us to mail in. Then Prescription Card Services (PCS) had us install those electronic terminals in our pharmacy, we didn’t have any paper to deal with. We then got our computers to interface directly with those insurance companies. At that time, one of my most quotable pharmacists Dick Treese said, “Once you leave those black boxes (modems) into your store, you will kiss your profession goodbye!”

Pharmacists got bamboozled for sure. As if the hassles with the insurance companies were not enough, we then got the DUR messages from the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) to assure that prescriptions for covered outpatient drugs are appropriate, medically necessary, and not likely to result in adverse reactions. We had to review (at no charge!) all of these messages and call physician offices if necessary. No problem, however, lots of jobs were available and salaries increased by leaps and bounds. My starting salary of $12.35 per hour in 1981 had tripled in less than 20 years.

Salaries like that attract interest in high school kids looking for a financially rewarding career. Universities answered the demand by creating more slots for these students. In 1981 when I graduated there were 72 schools of pharmacy, 40 years later there are 143 schools. Now I’m seeing job offers for new graduates about 2/3 of my current salary. Tuition is at least 17 to 20 times higher than when I graduated pharmacy school. Minimum wage midway through pharmacy school in 1978 was $2.65 per hour. A student would need to earn $52 per hour doing a minimum wage job to keep up with college pharmacy school inflation. Don’t forget to add an extra year of tuition for the PharmD program. We’ve sold out this profession to the pharmacy schools.

It’s my hope that 2020 is a profession changing year, starting with the schools of pharmacy. The average family size in my baby boomer generation was 3.67. Today’s family size is 1.9, nearly half of the family size when I was growing up. Half of the available kids as when I was growing up, with twice as many pharmacy school, has resulted in lower overall quality of graduating pharmacists. We need to be graduating a lot less student pharmacists. Wages have indeed stabilized, and I’m sure by the time I hang up my white lab coat, they will further decline. Again, we’ll be haggling about the price of the pharmacist.

Let’s take a clue from our fellow health care professionals: the physicians and dentists. We need to fix the “glut” of pharmacists. By selling out this profession, we will see a further depression in wages and benefits. We will also see an increase in the misery in the profession, by reduction in staffing, more responsibilities, and decreased job satisfaction.

I love this profession; I am so appreciative of the excellent academians that trained me and those training the future generation of pharmacists. Although there is a “glut” of pharmacists, there will never be an excess of excellent pharmacists who will never see the job satisfaction that I’ve seen throughout my career.

“We need to stop the deluge of pharmacists who will never see the job satisfaction that I’ve seen throughout my career.”

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Pete Kreckel, RPh, practices community pharmacy in Altoona, PA.
Telehealth-Based Program Increases Access to Opioid Treatment

All-cause deaths dropped 59% for adults who received methadone within 12 months of an opioid overdose, according to a study published in the *Annals of Internal Medicine*. The study also found that taking buprenorphine within 1 year of an overdose led to a 38% reduction in all-cause deaths.

These 2 statistics spurred Kavita Babu, MD, chief of medical toxicology at UMass Memorial Health Care in Worcester, Massachusetts, to launch a telehealth-based program to connect patients with credentialed clinicians who can prescribe medication-assisted treatment (MAT).

For context, the Massachusetts legislature passed a law in August 2018 requiring hospital emergency departments (EDs) to provide MAT to patients who present after an opioid overdose. To prescribe MAT, clinicians must have a Drug Enforcement Agency Category X waiver, which requires 8 hours of training. Seventy percent of UMass Memorial’s clinicians have participated in the training.

According to the CDC, Massachusetts ranked among the top 10 states with the highest rates of opioid overdose deaths. Synthetic opioids, mainly fentanyl, cause many of those deaths.

The patient experience
Since the UMass Memorial program launched in January, 1 patient has received a telehealth-based consult from a credentialed toxicologist. Babu described the patient as a young man with longstanding opioid use disorder. “He needed a prescription for Suboxone to continue treatment in a new facility,” she told *Drug Topics*.

Babu explained that, 5 years ago, the opioid overdose treatment protocol started with a first responder providing naloxone to reverse a patient’s overdose. After arriving in the ED, the patient was told by a physician to stop taking drugs, given a list of community resources, and discharged.

Today, at UMass Memorial - Marlborough Hospital, the patient presents in the ED, after getting naloxone. Then a clinician captures their history and their interest in MAT. If the patient agrees, the ED clinician connects the patient with one of the trained toxicologists on Babu’s team via a HIPAA-compliant telehealth platform.

The toxicologist’s goal is to empower the patient by getting them to take home a prescription for MAT, said Babu. After providing consent, the patient is sent home with a prescription and a handout prepared by the National Institute on Drug Abuse that asks a series of questions such as the number of hours since opioid use and the patient’s experience with symptoms such as yawning, nausea, and diarrhea. This guides the patient’s home induction of MAT, she explained.

Babu’s team developed an ED order set for buprenorphine-naloxone initiation.

Pharmacist engagement
Pharmacists have been at the forefront of creating access to naloxone and MAT, said Babu, especially if clinicians at their hospitals aren’t trained or are resistant to providing treatment.

For example, a pharmacist in a rural ED could struggle to expand access to MAT treatment without trained prescribers in the hospital, said Babu. Ensuring that clinicians receive training is part of the solution, but clinicians also need access to decision support to determine the appropriateness, as well as the timing and safety, of the approach, she added.

Hospital committees focused on pharmacy and therapeutics and ED oversight, where pharmacists are involved, should be interested in this offering, said Babu.

This initiative received $200,000 in funding from UMass Memorial Medical Group.
A Look Inside Harmons Pharmacy

Greg Jones, RPh, MBA, Director of Pharmacy Services, and his team are doing some amazing things in pharmacy.

Harmons is an upscale family-owned grocery chain with its headquarters in Salt Lake City, Utah. The chain features 19 grocery locations, 18 of them with pharmacies. Greg Jones, RPh, MBA, Director of Pharmacy Services, and his team are doing some amazing things in pharmacy.

First, the pharmacy department works closely with the company’s 7 registered dietitians to help pharmacy patients benefit from a variety of nutritional support programs. The dietitians work with all of the fresh food teams and the employee wellness program, as well as provide dietitian support to Harmons shoppers. This includes food tours, diabetes education, and a carefully orchestrated program that provides special shelf labels on products throughout the store that meet specific nutritional criteria.

Specifically, the dietitians place a special label on the shelf to highlight products that are gluten free, organic, local, or that are considered “Dietitians Choice.” The items tagged as “Dietitians Choice” meet nutritional guidelines for the healthy choices in specific categories across the store. The “Dietitians Choice” program makes it easy to find the healthy products—just look for the green tags on the shelves. Another one of the labels they use points out OTC or other health products that the Harmons’ pharmacist recommends. All in all, the program helps to build on the grocery chain’s image of providing fresh and nutritious foods.

Their second program, focusing on specialty pharmacy, is a bit more sophisticated and clearly positions Jones and his team as pharmacy trailblazers.

Harmons has a full-time sales representative that calls on prescribers all over the Salt Lake Valley. His job is to let health care professionals know about the specialty pharmaceuticals Harmons can supply and support services they provide.

The company website has a link to the documents for specialty disease states and medications designed for prescriber use in submitting prescriptions to the Harmons Specialty Pharmacy program. Prescribers can visit the site to see exactly what products Harmons has access to, obtain all the necessary prior authorization (PA) or other forms they need, and then write the prescription.

Jones says the range of services they provide allows them to help patients with HIV, hepatitis C, multiple sclerosis, and other conditions requiring specialty medications. The PAs and any co-pay assistance are coordinated by the central processing center for Harmons pharmacies. Harmons is providing specialty medication services through local pharmacies, building on their existing patient/pharmacist relationships. The Harmons Specialty Pharmacy program is currently accredited through the Center for Pharmacy Practice Accreditation.

Jones says this works well for everyone. The physician knows the Harmons team will do all that is necessary to meet the manufacturer requirements and help the patient qualify for insurance coverage or any other payment assistance. The patient gets to work with the Harmons pharmacist for all training and support they need.

Jones makes it clear that building such a system is not easy. Fortunately, he says they already had a central call/processing facility. The service is also supported through their partnership with KloudScript, who helps provide hub support services and specialty pharmacy services software. The challenges in specialty pharmacy remain, but the program continues to grow, showing 6-fold growth after 2 years.

Combine all this with the pharmacy’s wide variety of customer services and it is easy to see why Harmons pharmacies are special.
The Impact of Patents and Exclusivities on FDA’s Approval of Generic Drugs

Have you ever had a patient balk at getting their prescription filled when they find out the cost and then look to you for advice about their prescription? Or have you ever wondered why a generic manufacturer isn’t offering all strengths of a drug product for sale? Substituting a generic version of a brand-name drug can often be a cost-saving way for patients to purchase their prescription and maintain medication adherence. But what are some of the factors affecting whether a brand-name drug has generic competition?

The FDA knows that competition from multiple generic drugs for 1 brand-name drug can save money. In fact, multiple generic companies are often approved by FDA to market a single product. This creates greater competition in the marketplace, typically resulting in lower prices. Research shows that consumers may see a significant price reduction when there are at least 3 FDA-approved generics available.

The legal and regulatory framework that provides for FDA’s approval of generic drugs seeks to balance the public health goals of spurring innovation for new drugs and encouraging competition through generic drugs. Congress created the basic structure under which generic drugs are approved in the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments.

Generic drug competition with a brand-name drug can only begin after a generic drug has been approved by FDA. Patents and exclusivities for brand-name drug products are forms of protection for drug makers that may affect how and when a generic drug is approved and can be sold. The following are some of the overarching principles behind patents and exclusivities that affect the timing of the FDA’s approval of generic drugs.

What is a patent?
Patents can protect a company’s intellectual property investments (eg, by preventing other manufacturers from entering the market with the same product). Issued by the US Patent and Trademark Office (USPTO), patents can be issued before the drug has been approved by FDA.

When a brand-name drug applicant seeks FDA approval for a drug product via a New Drug Application (NDA), they must submit information to FDA specifying which patents claim the drug substance, drug product, and method of using the drug. The FDA publishes this information in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). These are referred to as “listed patents.” The FDA updates patent listings daily. The FDA’s role related to patents is essentially limited to ensuring that the patent information published in the Orange Book accurately reflects what the brand-name applicant submitted to the FDA. The FDA does not interpret patents or participate in patent infringement litigation between brand-name and generic drug companies.

What is an exclusivity?
The Hatch-Waxman Amendments are designed to achieve a balance between innovation and access to affordable drugs. To incentivize the development of brand-name drugs and new uses for approved brand-name drugs, the law provides sponsors of brand-name drugs with different marketing exclusivities, independent of patent protection, that could delay when a generic drug can be approved.

These exclusivities may be available for products containing new active moieties, new uses for previously-approved products, products treating rare diseases, products for which the brand-drug applicant conducted...

Rinku Patel, PharmD, FDA Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Generic Drug Policy, Division of Legal and Regulatory Support
studies in pediatric patients, and certain antibacterial or antifungal drugs intended to treat serious or life-threatening infections.

The exclusivities can also block the submission or approval of generic drug applications for set periods of time depending on the exclusivity. For example, if a brand-drug product is awarded exclusivity for a new use of a previously approved product, generic applications may be blocked from approval for 3 years from the time that the new use was approved by the FDA. The Orange Book provides information on what exclusivities a brand-drug product has. Information on how brand-drug sponsors qualify for these exclusivities is available on FDA’s website.

The Hatch-Waxman Amendments are designed to achieve a balance between innovation and access to affordable drugs.

**How do generic drug companies challenge a brand-name company’s patent?**

If there are patents listed in the Orange Book, the generic drug applicant must address each patent by “certifying” to the patents.

If the generic drug applicant believes that the listed patents are either invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic version, the applicant would provide a “paragraph IV” certification to that patent. The brand-name company or patent owner then can sue the generic drug applicant for patent infringement before the generic application is approved. Approved generic drug may be allowed to enter the market before the patent(s) expires if the generic drug applicant is not sued by the patent owner or brand-name company or if it is sued and either wins or the litigation is dismissed.

It is not uncommon for patent litigation between a brand-name company and the generic company to end with a settlement agreement between the parties. In a settlement agreement, the brand-name drug and generic drug companies agree on a date when the generic drug can go to market. The lawsuit is dismissed as part of the settlement agreement. Specific information related to settlement agreements and when a generic drug could go to market pursuant to such an agreement are not maintained by FDA and are not available in the Orange Book.

The Hatch-Waxman Amendments provide an incentive of 180 days of marketing exclusivity which can be granted to the “first” generic drug applicant that challenges a patent listed in the Orange Book for the brand-name drug by filing a paragraph IV certification and assuming the risk of having to defend a patent infringement lawsuit. A generic drug applicant can potentially retain eligibility for 180-day exclusivity even if it is not sued over its proposed generic drug or, if sued, the case is resolved or settled. This 180-day period starts when a “first” generic drug applicant starts marketing its product. The FDA does not interpret patents or participate in patent infringement litigation between brand-name and generic drug companies.

**FDA’s Orange Book Can Help**

Given the complex patent and exclusivity landscape surrounding generic drug approval, it can be difficult to know when a generic drug may enter the market. The Orange Book is a great resource to find out if there are patents or exclusivities that protect the brand-name drug and when those patents will expire. Patients will appreciate your knowledge of this information!
According to the National Institutes of Health (NIH), nonalcoholic steatohepatitis (NASH) is a form of nonalcoholic fatty liver disease (NAFLD). The NIH defines NAFLD as a condition in which a buildup of fat—not caused by heavy alcohol consumption—occurs in the liver. Patients with NASH also have inflammation of the liver, known as hepatitis, and resultant liver cell damage. NASH currently affects between 6.5 million to 16.3 million Americans.

**Current Management and NASH Pipeline Drugs**

According to the American Association for the Study of Liver Diseases, the management of NASH consists of treating liver disease as well as the associated metabolic comorbidities such as obesity, hyperlipidemia, insulin resistance, and type 2 diabetes.

There are currently no FDA-approved medications for the treatment of NASH, but the guidelines recommend lifestyle modifications like weight loss, pioglitazone (biopsy-proven NASH), and vitamin E as treatment options.

Empagliflozin (Jardiance) is showing promise for patients with type 2 diabetes and NAFLD based on positive results from the E-LIFT trial and study demonstrating the medication reduces liver fat.

Intercept has submitted the new drug application for obeticholic acid (Ocaliva) for the treatment of liver fibrosis due to NASH and was granted priority review by the FDA, with a target approval date of March 26, 2020.

Obeticholic acid has a unique mechanism of action as an oral farnesoid X receptor (FXR) agonist. It’s the only therapy the FDA has designated as a Breakthrough Therapy for NASH with fibrosis, according to results from the phase 3 REGENERATE study.

“If approved, obeticholic acid would be the first FDA-approved product for NASH, and it would likely have a year or more marketing head start over the rest of the pipeline,” said David Calabrese, RPh, MHP, senior vice president and chief pharmacy officer, OptumRx.

GENFIT is studying elafibranor, an oral medication currently in a phase 3 trial RESOLVE-IT for the treatment of NASH. After a favorable safety review, the study is continuing and expected to be completed in 2021. Elafibranor is a dual agonist of PPAR-alpha and PPAR-delta receptors, which both play an important role in numerous processes involved in the development of NASH and its comorbidities. The FDA has granted elafibranor fast track designation for the treatment of NASH.

“Allogren's cenicriviroc and Madrigal Pharmaceutical's resmetirom are in phase 3 trials and are anticipated to be approved in 2021-2022,” said Nicole Kjesbo, PharmD, BCPS, principal clinical program pharmacist, Prime Therapeutics.

The phase 3 study AURORA is currently recruiting an estimated 2000 participants to evaluate cenicriviroc for the treatment of NASH, with topline results expected in the fourth quarter of 2020. Resmetirom would be a first-in-class oral thyroid hormone receptor-beta selective agonist, and the phase 3 study MAESTRO-NASH began March 2019. The endpoint is resolution of NASH after 1 year of treatment. In addition to the drugs mentioned, Kjesbo revealed there are at least 10 other drugs for the treatment of NASH that are in Phase 2/3 trials and are anticipated to be approved in 2021 and beyond.

**Looking Ahead**

“Many of the pipeline drugs are being developed by different manufacturers and some manufacturers are developing multiple drugs for NASH,” said Calabrese. “Therefore, there may be potential for combination therapy down the road which would further increase the future cost of treatment.”

“This is going to be an emerging category in the coming years,” said Kjesbo. “Currently, pharmacotherapy is reserved for NASH patients with fibrosis; it will be interesting to see if lifestyle changes will continue to be the first-line treatment over medications.” According to Kjesbo, analysts have forecasted the market for NASH drugs could reach $20 billion by 2025.

Erin Johanek, PharmD, RPh is a staff pharmacist at Southwest General Health Center, Middleburg Heights, Ohio.

For references, visit DrugTopics.com
NEW DRUG REVIEW

Ubrogepant: A Novel Drug Mechanism for Migraine Treatment

By Kathryn Wheeler, PharmD, BCPS

On December 23, 2019, the FDA approved ubrogepant for the acute treatment of migraine with and without aura in adult patients. Ubrogepant is a calcitonin gene-related peptide (CGRP) receptor antagonist. CGRP is a protein released when the trigeminal nerve is activated. Binding of CGRP to its receptor is associated with blood vessel dilation, inflammatory mediator release, and transmission of pain stimulus to the central nervous system—mechanisms involved with migraine pathology. Blocking CGRP from binding to its receptor is a novel mechanism for migraine treatment.

Efficacy

Ubrogepant was approved based on the results of 2 randomized, double-blind, placebo-controlled trials. In these trials, 1439 participants were randomized to placebo, or 50mg of ubrogepant in both trials. Some patients (23%) were taking preventive migraine therapies, but none were on medications affecting CGRP. In study 1, participants were randomized to an additional 100-mg arm. In both trials, participants were instructed to treat a migraine of moderate-to-severe intensity with the study drug. A second dose of study drug or the participant’s usual acute migraine therapy could be administered 2 to 48 hours after the initial dose as needed. In both studies, a comparison of pain and most bothersome symptom (MBS) at 2 hours post-dose for ubrogepant versus placebo serves as the primary outcome. Both studies showed that participants taking ubrogepant demonstrated greater rates of absence of pain or MBS at 2 hours post dose compared with placebo. In study 1, both doses of ubrogepant were associated with reduced occurrence of photophobia or phonophobia compared with placebo.

Safety

The most common adverse effects seen in studies with ubrogepant are nausea and somnolence. Ubrogepant is primarily eliminated via metabolism by cytochrome P450 3A4 (CYP3A4). Administration of ubrogepant is contraindicated in patients taking a concomitant strong CYP3A4 inhibitor, as this will significantly increase exposure to ubrogepant. Patients taking concomitant moderate 3A4 inhibitors should administer a lower dose (50 mg) and avoid a second dose within 24 hours of the first dose. Ubrogepant is also a substrate for BCRP and P-gp transporters. Based on the findings of clinical interaction studies, patients taking concomitant BCRP and/or P-gp inhibitors should utilize a lower dose of ubrogepant to limit exposure. Patients with severe hepatic impairment (Child-Pugh class C) should administer the reduced dose. Patients taking strong CYP3A4 inducers, or who have end stage renal disease (CrCl <15 mL/min) should avoid taking ubrogepant. There are no data regarding the safety of treating more than 8 migraines in a 30-day period or on the effect of ubrogepant on a breastfed infant.

Dosing

Ubrogepant is approved for use in adult patients as both 50-mg and 100-mg tablets to be administered as a single dose as needed for migraine symptoms. It can be administered with or without food. A second dose may be administered no sooner than 2 hours after the initial dose, with a maximum dose of 200 mg per 24 hours. Administration of ubrogepant with a high-fat meal may reduce peak drug concentration by 22% and delay the peak drug concentrations by 2 hours without an overall change in the AUC.
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