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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.
In its Notice of Proposed Rulemaking, DEA proposes to reduce the amount of oxymorphone (Opana) produced by 55%, fentanyl by 31%, hydrocodone (Vicodin) by 19%, hydromorphone (Dilaudid) by 25%, and oxycodone (Oxycontin) by 9%.

Combined with morphine, the proposed quota would be a 53% decrease in the amount of allowable production of these opioids since 2016.

Conversely, DEA is proposing to increase the amount of marijuana that can be produced for research from 2,450 kilograms to 3,200 kilograms—almost triple the amount produced in 2018.

The Proposed Aggregate Production Quotas and Assessment of Annual Needs addresses more than 250 Schedule I and II controlled substances and three List I chemicals, which include ephedrine, pseudoephedrine, and phenylpropanolamine. “This reflects the total amount of substances needed to meet the country’s legitimate medical, scientific, research, industrial, and export needs for the year and for the maintenance of reserve stocks. DEA endeavors to set production limits at a level required to meet these needs, without resulting in an excessive amount of these potentially harmful substances,” the agency said.

Individuals can submit public comments on the proposed APQ until 11:59 p.m. on October 10, following the instructions in the Notice. After taking the comments into account, DEA will publish another notice later in the year informing the public of the established APQ.

– By Christine Blank

DEA to Slash Opioid Production

Small doses

By Drew Boxler, associate editor
Small doses

NYC Measles Outbreak Declared Over

The number of measles cases in the U.S. has skyrocketed and has reached the greatest number of cases reported since 1992, according to the CDC. Simultaneously, New York City health officials said the measles outbreak there has ended.

From January 1 to August 29, 1,234 individual cases of measles have been confirmed in 31 states, says the CDC. Nineteen additional cases were reported in the last week of August.

On September 3, New York City Mayor de Blasio and Health Commissioner Dr. Oxiris Barbot announced the end to the measles public health emergency declared on April 9 for parts of Brooklyn. Measles outbreaks are typically declared over when two incubation periods for measles (the equivalent of 42 days) have passed since the last infectious day of the last persons with measles in affected areas, according to a statement from Mayor Bill de Blasio.

“Ending the measles outbreak required extensive collaboration with community organizations and Jewish leaders. They helped encourage vaccinations and achieve record immunization levels in parts of Brooklyn,” de Blasio says. “As we head back to school this week, we just remain vigilant. To keep our children and communities safe, I urge all New Yorkers to get vaccinated. It’s the best defense we have.”

Pharmacists have been on the frontline of fighting the measles outbreak, by offering both information and vaccinations.

“We are seeing increased demand for vaccination and pushback on anti-vaccine groups,” Mitchel C. Rothholz, RPh, MBA, chief strategy officer for APhA, told Drug Topics in March. “At a minimum, pharmacies are serving as additional outlets for information to the public about the importance of MMR vaccine. They are a conduit to address some of the misinformation that is circulating.”

Meanwhile, CDC found that more than 75% of the cases this year are linked to outbreaks in New York. “Measles is more likely to spread and cause outbreaks in U.S. communities where groups of people are unvaccinated,” CDC says.

So far this year, 125 of the people who got measles this year were hospitalized, and 65 reported having complications, including pneumonia and encephalitis.

Senate Finance Committee Wants Trump Action on DIR Fees

Several pharmacy groups lauded a letter from the chairman and a majority of the Senate Finance Committee urging the Trump administration to reform direct and indirect remuneration (DIR) fees.

The letter, from Senate Finance Committee Chairman Chuck Grassley (R-IA), Ranking Member Ron Wyden (D-OR), and more than 80% of the Committee sent to Department of Health and Human Services (HHS) Secretary Alex Azar and Centers for Medicare and Medicaid Services (CMS) Administrator Seema Verma, requested that they use regulatory authority to reform direct and indirect remuneration (DIR) with respect to pharmacies under the Medicare Part D program.

Eight organizations representing pharmacy’s collective voice—including NACDS, NCPA, and APhA—lauded the request as an essential part of a regulatory and legislative push to remedy a problem that becomes more dire with each passing day.

In the letter, HHS is urged to “revive the pharmacy DIR reforms included in [CMS] November 30, 2018 proposed rule, ‘Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,’ (CMS-4180-P), and finalize them for plan year 2021.”

“CMS documented an extraordinary 45,000 percent increase in DIR fees paid by pharmacies from 2010 to 2017. This is an untenable trend for pharmacies and causes higher prices for beneficiaries at the pharmacy counter,” the senators wrote in the letter. “Moving forward with the proposed reforms, we urge the agency to redefine ‘negotiated price’ to include all pharmacy price concessions at the point-of-sale and establish a broader definition of ‘price concession’ to bring clarity to the true price Medicare pays for a Part D drug and provide financial relief to beneficiaries, many of whom struggle to afford their medications.”

“This letter reflects the strong bipartisan recognition that pharmacy DIR fees must be stopped to prevent harm to patients and to the pharmacies that serve them – harm that is egregious and escalating. The Senate Finance Committee members stated clearly the importance of this issue to patients and to pharmacies; the concerns regarding Medicare Part D plan and pharmacy benefit manager (PBM) practices; the economic factors that are necessary to consider when accurately evaluating the importance of DIR fee relief; and the policies that are necessary to deliver true reform,” the pharmacy organizations said in a statement.

In addition to NACDS, NCPA, and APhA, the National Association of Specialty Pharmacy, the Food Marketing Institute, the National Grocers Association, the National Alliance of State Pharmacy Associations, and American Society of Consultant Pharmacists signed on to the joint statement.

“This is the breaking point, and there is no alternative but for both legislative and regulatory approaches to deliver a timely and comprehensive solution to change the definition of ‘negotiated price’ and to establish standardized pharmacy quality metrics,” the groups said. “DIR fee relief is absolutely essential for patients and for pharmacies now. It also is a necessary component of any effort to reduce patients’ out-of-pocket costs, to enhance transparency, and to foster the sustainability of Medicare.”

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**Small doses**

**Pharmacists Indicted in Extensive “Pill Mill” Scheme**

Pharmacy owners, managers, and pharmacists were among those indicted in a sweeping DEA sting on “pill mill” clinics and pharmacies. The actions of 41 individuals—which also include medical providers, clinic owners, and drug dealers—resulted in the diversion of around 23 million oxycodone, hydrocodone and carisoprodol pills, said DEA in a statement.

*This type of criminal activity is, in part, what is fueling the 68,500 overdose deaths per year across the US* 

**Walmart Tests Health Clinics**

Walmart is testing a free-standing health clinic concept, called Walmart Health, which offers low-cost primary care, mental health counseling, dental care, lab tests, immunizations, x-rays, audiology, and other services.

*The cost per visit is between $59 and $99 for patients without insurance; Walmart Health also accepts several major insurance plans. Test sites will launch in Dallas, GA, before expanding in the future.*

**FDA Approves First Drug Under Project Orbis**

FDA granted accelerated approval to Lenvatinib (Lenvima, Eisai) in combination with pembrolizumab (Keytruda, Merck) for the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.

*Project Orbis: the new, international partnership between the FDA’s Oncology Center of Excellence, the Australian Therapeutic Good Administration, and Health Canada.*

*Goal: Increase collaboration among international regulatory agencies that will allow patients to receive earlier access to new cancer treatment products available in other countries where regulatory submissions may be delayed, regardless of whether or not the product has gained FDA approval.*

**CDC, AAP Release New Childhood Flu Vaccine Recommendations**

Primary changes include
- Afuvia Quadrivalent age indication expanded from five years and older to six months and older. The dose volume for Afuvia Quadrivalent is 0.25 mL for children aged six through 35 months and 0.5 mL for everyone three years and older, the CDC said in its August 23 Morbidity and Mortality Weekly Report.
- The dose volume for Fluzone Quadrivalent for children six months through 35 months raised to at least 0.25 mL or 0.5 mL. The dose volume for Fluzone Quadrivalent is 0.5 mL for everyone three years and older, the CDC said.
- Both inactivated influenza vaccine (IV) and live attenuated influenza vaccine (LAIV) are options for influenza vaccination in children, with no preference, AAP said.
- Composition updates: A(H1N1)pdm09 and A(H3N2) components of the vaccine are new for this season. The B strains are unchanged from the previous season, according to the AAP.
- All pediatric influenza vaccines will be quadrivalent vaccines, and no trivalent vaccines are expected to be available for children this season. The age indication for some pediatric vaccines has been expanded, AAP said. There are now four egg-based quadrivalent inactivated influenza vaccines (IV4s) licensed by the FDA for administration to children six months and older, one inactivated cell-based quadivalent inactivated influenza vaccine (cIIV4) for children four years and older, and one quadrivalent live attenuated influenza vaccine (LAIV4) for children two years and older.
- Children six months through eight years of age who are receiving influenza vaccine for the first time or who have received only one dose before July 1, 2019, should receive two doses of influenza vaccine ideally by the end of October, and vaccines should be offered as soon as they become available, AAP said. Children needing only one dose of influenza vaccine, regardless of age, should also receive vaccination ideally by the end of October.

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

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Prevent Burnout

How to manage stress in the pharmacy.  By Keith Loria

Perhaps it goes without saying, but working in a pharmacy is stressful. The overhead noise that often present in pharmacies, the fluorescent lights, ill patients or ill-tempered colleagues can make for a very stressful work environment.

Unlike other stressful work environments, though, pharmacists are responsible for the lives of the people they serve. Stress at work can affect their emotional and mental clarity, cognitive alertness, and can make it difficult to concentrate—all of which increase the likelihood of accidents. A minor alteration in dosage or accidentally administering the wrong medication can truly mean life or death for a patient.

And not only does stress put pharmacy patients in danger, it’s also detrimental to the pharmacist. It’s well documented that stress contributes to deadly health problems including (but not limited to): high blood pressure, heart disease, diabetes, and obesity.

Why So Stressed?
Amber Cann, PharmD, has been a pharmacist for 19 years and currently practices in the Louisville, KY greater metro area. Over the years, she’s worked at a hospital pharmacy, an independent/compounding community pharmacy, and a big chain store pharmacy. The one thing that’s been prevalent at all three jobs? Stress.

“Retail pharmacy is particularly stressful right now. The metrics on which the pharmacist performance is based does not relate to patient safety,” she says. “Major chains insist pharmacists fill a quota of prescriptions per day, in addition to calling a quota of patients to remind them of refills, asking each patient to get a flu shot, administering flu shots to those patients who agree and completing paperwork related to inventory and controlled substances.”

A problem, Cann says, is chains advertise to patients that prescriptions can be done in 15 minutes or less, when that isn’t a reasonable time when there are many prescriptions in the queue and vaccinations to administer. Plus, many are dealing with physicians who incorrectly write prescriptions, which requires the pharmacist to call to get clarification.

“Patients get angry at—and sometimes even physically threaten—pharmacists when their prescriptions are delayed due to things out of the pharmacist’s control, such as insurance prior authorizations and incomplete prescriptions,” Cann says. “As pharmacist hours are cut, the job doesn’t provide the financial security it once did.”

While working in retail pharmacy, she was threatened several times by patients, including one who entered the pharmacy and grabbed her by the lapel of her lab coat and another who waited until the pharmacy closed and followed her to her car.

“On several occasions, I was spat on by patients, and had objects thrown at me,” Cann says. “On countless occasions, I was called vulgar names and insulted by patients. These are the sort of working conditions faced daily by many pharmacists I know personally, too. Is it any wonder pharmacist stress and burnout are at an all-time high?”

The Roads to Stress
Hussein El-Khatib, PharmD pharmacist and owner, Toledo Family Pharmacy in...
Perfume Burnout

“Retail pharmacy is particularly stressful right now.” AMBER CANN, PHARMD

Toledo, OH, says the pharmacy business is a stressful job for the sole fact that pharmacists are dealing with patients’ lives and the margin for error should be zero, but that’s virtually impossible.

“Mistakes will happen sooner or later, and you only want to hope that you don’t make a deadly mistake,” he says. “For the past 10 ten years, I’ve been filling on average about 100,000 prescriptions per year—that’s a million prescriptions. So, if the margin of error is 0.0001%, that’s 10 prescriptions every year you’re making a mistake and that mistake could result in a deadly scenario.”

The majority of stress in an independent pharmacy, he says, comes mainly from three different sources: The first is business related: running an independent business is a challenge by itself, let alone running an independent pharmacy in the age of low reimbursements and Direct and Indirect Remuneration (DIR) fees.

“One of the biggest stressors for a pharmacy owner is cash flow and profitability, which is the only way a pharmacy door can stay open,” El-Khatib says. “With what’s going on in the industry right now, you have to innovate, invest in the future and adapt to the new model of care that is being put together by the CMS.”

The second obstacle is effective patient communication. While independent pharmacy patients are very pleasant for the most part, and you can build a great rapport with them, El-Khatib says they can get upset for a lot of reasons that normally have nothing to do with the pharmacy.

For example, a medication may not be covered by insurance, covered with high co-pay, needs a prior authorization or early fills, or any other of a host of factors outside of a pharmacy’s control.

“Patients may not understand the rules and regulations surrounding controlled versus non-controlled substances or why we can’t fill a cash prescription when it was just filled a week ago,” he says. “Complaints and competition can cause patients to seek to transfer out of your pharmacy.”

The third obstacle is finding good technicians. Quality and experienced techs are very hard to find and train.

“If you own a long-term care pharmacy and pick up a huge account, you can go from filling zero prescriptions to 5,000-7,000 that need blister packaging on a monthly basis, in a matter of a week,” El-Khatib says. “You can’t let such opportunities pass by and if you can’t find good staff or if you didn’t prepare beforehand to train someone, then you might experience difficulties that cause stress.”

Inna Lukyanovsky, PharmD, started her career in the early ’90s working in a family pharmacy, and she’s worked for a big retail chain in Brooklyn, NY for more than 20 years.

She says a lot of stressful situations fall on the shoulders of retail pharmacists, such as the hours pharmacists put in, the lack of opportunity to take bathroom breaks, angry customers, paperwork, deadlines, unpredictable prescription flow, insufficient amount of help like techs and cashiers, poor working locations that lack natural light, and many more.

“Being a pharmacist carries tremendous responsibility as a professional,” she says. “Your job is not only to dispense, but to clinically assess if the medication is not therapeutically duplicated, there are no interactions, no mistakes with the doses, no allergies to the class of drugs, no contraindications for the drug, no underdosing, no overdosing, vaccination administration, and so much more. That’s a lot of weight.”

Finding Help

Over the years, Cann has de-stressed with other pharmacists on days off, getting together to vent about expectations, share stories, provide and receive support. She belongs to a number of pharmacist-only Facebook groups where information and support is shared and also attends professional meetings where she can network with other pharmacists and other employers.

During the time when Cann worked the longest hours in retail pharmacy—as much as 14 hours a day, 5 to 7 days a week—she sought the help of a therapist to work through issues with work stress and to learn ways to diffuse difficult situations at work.

“I once took an online course in conflict management to better deal with...
coworkers who behave in unprofessional ways and with patients who escalate situations,” she says. “Good communication among pharmacy staff members helps the workflow run smoothly. Exercise is a must to release tension and help counter those long hours at work.”

What has worked for El-Khatib to relieve stress has been creating opportunities to gain more business and attract more customers, and manage inventory and cash flow. He has also made an effort to build banking relationships in order to be able to increase business credit when cash flow is needed, so that lines of credit or loans can be taken out.

Over the years, Lukyanovsky has tried many avenues to relieve stress and keep job burnout from creeping in.

“Mindset, meditation, planning, and preparing all worked for me. I would meditate at night for an easy flow and good energy day the next shift. I would envision the flow of my next day, being smooth and steady” she says. “I would intend for a good day the morning of the shift, listen to positive affirmations and start the day right. Also, giving compliments or saying nice things to your customers before they even say something can work even for your meanest client.”

Lukyanovsky learned many of those options through self-help books and coaches.

“I was sick at some point so my functional medicine practitioner taught me his method of how to resolve physical stress through functional medicine and I was so impressed that I started helping others, even fellow pharmacists to help them resolve their physical stress,” she says. “I also worked with a hypnotherapist and she also helped me tremendously dealing with work related stress, understanding and assessing stressful situation and resolve it instead of fuming.”

Advice from Stress Experts

Andrew Alexander, a stress-management consultant, explains at the most basic level, stress is a collection of emotions building up within the body and when the emotions build up too much, they need a way to channel them out in order to release them.

“Different people do different relaxing techniques,” he says. “An example is some form of exercise or other physical activity (basketball, tennis, cardio kickboxing, etc.). Anything that allows you to channel this energy into something outside you. Journaling, writing, art, and creativity are ways other people do it. It’s a matter of what works best for you.”

For pharmacists, he recommends that when stress builds up, take a quick walk around the outside of the store to get a change of scenery. Even a little break, he says, can help reset someone’s emotions when they build up during work.

Meditation is another thing that can help, but most people have an extraordinarily hard time meditating alone in complete silence. Instead, a pharmacist can opt for a meditation app or a YouTube-guided meditation that will lull them into a calmer state of mind.

As with anything overwhelming in life, it’s important to create a list of priorities in order to avoid burnout. This can be even more relevant for pharmacists, where pressure is high and stressful situations are a daily occurrence.

Adina Mahalli, a certified mental health consultant and family care specialist with Maple Holistics, Farmingdale, NY, says a great thing for pharmacists to do is create a chart that outlines the importance and urgency of tasks. This can give you a sense of purpose and a place to begin when it comes to dealing with a heavy workload.

“This organization can go a long way in not only mitigating stress but providing you with a sense of accomplishment as tasks are completed,” she says.

An important step in mitigating stress is breathing. Though it may feel like the pharmacy will go up in flames if you take a five-minute break, taking a time-out for some deep breaths can help to reduce burnout and increase productivity.

“Deep breathing activates your parasympathetic nervous system which helps with stress reduction and improves focus,” Mahalli says. “This means you can get back to your task feeling relaxed and focused.”
Pharmacists Embrace New Technologies

The technologies making an impact on pharmacy. By Karen Appold

Technology use in healthcare is growing with the increased use of electronic health records and health informatics, and pharmacy is no exception. Pharmacists should embrace the innovations technology can offer in order to enhance patient engagement, improve workflows, increase patient safety, and simplify communication.

Automation and Patient Engagement

One of the biggest challenges consumers face is incorporating complex and multiple medication regimens into their daily lives. “It’s important to design behavioral and therapeutic interventions that engage patients throughout their journey from their first prescription fill through refill,” says Omri Shor, co-founder and chief executive officer, Medisafe, a medication management platform. Today, various platforms assist with dosing, how to take specific medications such as injections, and how to mitigate adverse effects.

For example, Shor recommends designing interventions for selective serotonin reuptake inhibitor patients in the beginning of treatment that reinforce adherence, since patients may not initially feel a medication’s effects because it takes time to titrate. Interventions might include digital messages, reminders, or even surveys through the company’s app to understand a patient’s needs. Equally important is educational content about medication applications, such as how to properly inject medications, connections to care support, and condition-related measurement trackers.

Another technology gaining popularity is the central fill automation machine, which can fill medicines in high volumes in lieu of a technician or pharmacist, says Elizabeth Unni, PhD, MBA, BPharm, chair and associate professor, Social, Behavioral, and Administrative Sciences, Touro College of Pharmacy, New York.

Central fill automation machines are especially beneficial for medication refills: Based on the first fill of a medication, subsequent fills are automatically filled for verification and dispensing. In addition to lowering operating costs and reducing dispensation errors, this can save significant time for pharmacists, allowing them to work on more clinical aspects of medication dispensing, such as patient counseling or medication therapy review.

Automation isn’t only for pharmacists, however. Machines can now dispense medicines for patients, similar to vending machines. Instead of waiting at the pharmacy window for a technician or pharmacist to hand over a bag of medicine, a patient can access a machine inside the pharmacy, Unni says. Pharmacy personnel scan and load filled medicine bags into the machine.

If a patient is interested in using the machine, they are registered within the pharmacy and given a unique pin number to access their medication bag and pay electronically for their medicine. Before receiving their medication, a patient must accept or decline counseling by the pharmacist. If counseling is requested, the patient can pick up a phone located on the machine and be connected to a pharmacist. “These machines can make prescription dispensing windows less crowded and allow patients to pick up their medications at their own convenience, as long as the store is open, even when a pharmacy is closed,” Unni says.

In a hospital setting, automated dispensing cabinets are used to increase workflow efficiencies and patient safety, Unni says. Unit dose medicines are prepared and stored in these cabinets, which a nurse can access after a pharmacist verifies the prescription order entered by a physician.

AI Technologies

Pharmacies are using the large amount of data they generate in a variety of ways. The current pharmacy management systems used through pharmacy benefit managers have information about each patient’s prescriptions and prescription pick-up habits, Unni says. Several health insurance companies use this data to flag patients who haven’t picked up their medicine in recent months—an indication of medication non-adherence. This provides an opportunity for the pharmacist to either call or speak with the patient about the necessity of taking their medicine as prescribed.

Additionally, some pharmacies and
**TECHNOLOGY**

**FUTURE TECHNOLOGIES**

Looking ahead, technologies will continue to transform the pharmacy industry in positive ways.

Fisher expects pharmacy dispensing to become more automated in the next decade. With electronic prescribing becoming the norm, pharmacists will no longer need to manually interpret prescription data or enter it. “As dispensing machines and systems become smarter, the whole process will be mostly automated with minimal clinical oversight,” she says.

This will force pharmacists to evolve. They will need to embrace their place in clinical roles, such as medication therapy management programs, patient education, or health information technology. “Pharmacists can make a huge impact on drug costs and patient education, which impacts overall compliance and healthcare outcomes,” Fisher says. As technology evolves, programs will accurately target the most needy and costly patients.

On another front, Benjamin M. Bluml, RPh, senior vice president, Research and Innovation, American Pharmacists Association Foundation, which is focused on patient-centered, team-based care, has predicted that through new technology innovations medications will be customized to an individual patient’s genome, health status, and point-of-care needs via 3D printing. This may even include all-in-one pills for some patients.

The supporting technologies for this revolution are already in place. Hard work from clinicians on data aggregation and standards that support individualized care is ongoing through the Clinical Pharmacogenetics Implementation Consortium (CPIC), Bluml says. Technology companies are also working on innovations that will increase the variety of medications available for 3D printing. This may even include all-in-one pills for some patients.

Finally, with many grocery stores containing pharmacies and with a focus toward lifestyle management for chronic disease conditions, a new technology that could emerge in the next decade is linking an individual’s shopping habits to their prescriptions. “By using store loyalty cards, consumer shopping habits can be captured, which can be connected to their prescriptions for point-of-buying suggestions,” says Unni. For example, if a patient has a prescription for cholesterol-lowering medicines and is buying red meat, the technology (in the form of a mobile app) could inform the individual about red meat’s fat and calorie content and could make recommendations about the appropriate use of that food, even including healthy recipes.

health insurance companies are using big data to predict the risk of medication non-adherence, Unni says. This medication adherence prediction model is based on several variables, such as patient demographics, the number of medications a patient takes, out-of-pocket costs for medications, and past refill habits. When a patient is identified as high-risk for medication non-adherence, a pharmacist provides them with additional counseling to reduce the possibility of non-adherence. They focus on educating the patient about the importance of adherence, the need for the medicine, what to expect for treatment outcomes and side effects, cost concerns, and so forth.

In clinical pharmacies, in collaboration with physicians, big data is now used to develop algorithms to predict treatment outcomes or medication errors. Based on past outcomes and medication errors with various patient and condition characteristics such as age, gender, duration of disease, and severity of disease, risk models are developed to determine treatment outcomes and medication errors, Unni says.

Medisafe’s AI technologies are based off of machine learning analyzing more than 2 billion managed doses. The company leverages this data to identify persona types based off of behaviors such as reasons for non-adherent behavior, demographics, digital profiles, and therapeutic needs. “Once patients match persona types, then the power of AI guides patients through their personalized journey in their medication management needs,” Shor says. For example, periodic surveys or interventions check in with patients to assess their progress. If needed, persona-based management designs will change to meet patient’s needs.

Pharmacists are also using AI to monitor and prevent opioid abuse. “Incorporating AI can remove some of the burden from healthcare providers and improve patient safety,” says Rachael Fisher, PharmD, senior clinical implementation analyst, Wolters Kluwer, Health, which provides evidence-based health information and technology. Nationwide databases and prescription history can be used alongside AI to identify patients at risk for opioid misuse or patients who are doctor shopping, which could be an indicator that they are obtaining multiple controlled substance prescriptions illegally. Also, AI can identify physicians who overprescribe opioids, so education can be recommended.

Many state-specific laws have been created in response to the epidemic. “Pharmacists can use AI to assess compliance of local laws in addition to national recommendations from organizations such as CMS and CDC,” Fisher says. “The environment is ever changing; AI can help providers be more vigilant, effective, and improve overall opioid monitoring and safety.”
RESPIRATORY

New Pneumonia Drug Could Be Game-Changer

Why a new treatment to combat drug-resistance matters.  By Barbara Hesselgrave

Use hand sanitizers, cover your mouth, wash your hands, wear a mask—the byword messages of public health agencies are upon us once again as temperatures drop. In an era of increasingly drug-resistant pathogens, widespread efforts to prevent the spread of infectious disease are laudable.

Nonetheless, providers who treat severe respiratory illness say it is particularly troublesome for older people whose bout with influenza often results in community-acquired bacterial pneumonia (CABP). Depending on the bacterial strain, resistance is widespread, making the infection a tough contender to cure at any age—but especially in older people.

This season, however, providers will have a new and better choice for the treatment of CABP, a disease whose risk not only increases with age but is a significant burden of illness for about 5 million people in the U.S. each year. A study of claims data from nearly 2 million individuals 65 years and older enrolled in a Medicare Advantage Plan found that, in 2015, the CABP-related hospitalizations incurred medical costs in excess of $18,000 with an average length of stay of 5.6 days.

In August, the FDA approved XENLETA (lefamulin, Nabriva Therapeutics plc), a new antibiotic that is forecast to have a significant impact on patients with CABP and is hailed as a significant breakthrough for the treatment of antibiotic-resistant disease.

Nabriva’s chief commercial officer (CCO), Francesco Maria Lavino, PharmD, reports, “This is tremendously exciting as not only is XENLETA a new molecule, it is a new molecule in a brand-new class of IV and oral anti-infective drugs, and this has not happened in almost 20 years. And, it is also the first new-class antibiotic that has been approved in both oral and IV form which is very important because it gives physicians wider treatment options.”

XENLETA is available for oral (600 mg every 12 hours) and intravenous (150 mg every 12 hours) administration with a short 5-to-7 day course of therapy.

He explains the unique mechanism of action of this novel molecule—lefamulin.

“The drug inhibits the bacterial protein synthesis by binding the 50S ribosomal subunits through multiple interactions, and it is in the way it binds to the ribosomal site that is different from any other antibiotic. This results in a low risk of developing resistance to XENLETA as well as a low risk of developing resistance to older antibiotic classes such as the beta-lactams, fluoroquinolone, macrolide, and tetracycline antibiotic classes.

“When you have multiple binding sites it becomes more difficult for the bacteria to mutate to prevent the antibiotic from working and at the same time, retain its fitness and ability to replicate. Overcoming drug resistance is a function of inhibiting bacteria that have created already-created mechanisms to resistance to other drugs. By inhibiting the bacteria with this type of interaction, which is the hallmark of this new molecule, we achieve both effective treatment outcomes and overcome propensity toward resistance at the same time.”

The recent Antimicrobial Agents and Chemotherapy article reported on the efficacy of lefamulin as the first semi-synthetic pleuromutilin antibacterial for intravenous and oral treatment of community-acquired bacterial pneumonia. Results from the 2015-2016 SENTRY Antimicrobial Surveillance Program state that XENLETA (lefamulin injection, tablets) was highly active against the most common pathogens in pneumonia—including strains that are multidrug resistant.

Lefamulin shows efficacy against multidrug resistant strains:

- Streptococcus pneumoniae
- Staphylococcus aureus
- Haemophilus influenzae
- Legionella pneumophila
- Mycoplasma pneumoniae
- Chlamydia pneumoniae

Source: Antimicrobial Agents and Chemotherapy

New Antibiotics Needed

Julio A. Ramirez, MD, professor of medicine, and chief, Division of Infectious Diseases at the University of Louisville underscores the need for a new class of antibiotics that fight resistance.

“The bacteria that have caused CABP have remained the same, but each one
of these bacteria have developed the capacity to fight against the antibiotics that we regularly use to treat pneumonia.”

He says the bacteria that cause pneumonia typically classified as either typical or atypical pathogens.

“To treat these two groups of bacteria in hospitalized patients, sometimes we use two different classes of antibiotics. The advantage of XENLETA is that we can treat these two types of bacteria with a single antibiotic. Once patients are hospitalized with CABP, we can start IV XENLETA as a single antibiotic therapy; once patients improve, we can use the same antibiotic in an oral formulation and achieve an early hospital discharge.”

Ramirez says the launch of XENLETA is very important as it offers a new class of antibiotic with documented clinical efficacy in patients with CABP.

“This is a very common infection and is considered one of the primary infection-related causes of death in the U.S.,” he says.

Lavino underscores this importance for new options, saying the drug is “going to be an ideal choice for CABP patients and will give providers a well-tolerated and effective option, particularly considering that 30% to 60% of S. pneumoniae are reported to be macrolide resistant.”

From a clinical perspective, he says physicians can offer patients who show up to the ER an opportunity to initiate therapy with an oral medication and prevent hospitalization if their condition does not warrant admission.

“Even if they are admitted for a day or two, they can start on the IV XENLETA and then go home and continue on the oral therapy. Many times, physicians will admit patients, but they know that macrolide treatment has resistance and while the efficacy of broad-spectrum fluoroquinolones on CABP are excellent, there are many boxed warnings that often deter a physician’s use of this drug,” Lavino adds that this continuity of treatment—the same drug from hospital to home—is important.

Philip Giordano, MD, FACEP, vice chairman of Orlando Regional Medical Center Department of Emergency Medicine says he is “very excited to have XENLETA added to our pneumonia armamentarium.”

The drug, Giordano says, is particularly exciting because it plays into the trend of moving patients into outpatient management as much as possible. “Outpatient management reduces costs, increases patient satisfaction, and avoids exposing patients to nosocomial infections.”

“Currently, many patients with CABP are admitted to the hospital solely because of the lack of confidence in currently available oral agents. The introduction of a new antibiotic with potency, ease of use, and a safety profile that clinicians can be confident in will increase the opportunities for outpatient management,” Giordano says.

One study, Lavino says that LEAP 2, showed that in just five days of monotherapy XENLETA’s effectiveness for CABP is the same as seven days of moxifloxacin.

“Along with the appropriate spectrum of coverage for the right bugs, this is another important principle of stewardship, to treat in the shortest duration to be effective,” says Lavino. “So you can send more patients home and prevent hospitalizations and the costs incurred, as well as the stress and risk of that event upon the patient.” He adds that the current median length of a CABP-related hospital stay is three to four days and that direct costs of pneumonia is estimated to be approximately $17 billion in the U.S.

He reports that Nabriva “initiated a lot of pre-work to the launch by profiling the main accounts and the managed care team has been engaging payers to accelerate coverage. XENLETA is covered by Medicare for inpatient use and most commercial plans follow that lead since most hospitalizations are treated under a DRG single payment system and in the next few months we expect the majority of commercial plans to review and approve the drug.”

The company says the wholesale acquisition (WAC) price is $205 per IV treatment day and $275 per oral patient treatment day.

However, adopting a new therapy often poses reimbursement challenges to the system and Giordano says, “Differences in the way hospitals add to their formularies can affect the adoption of a new intravenous drug. When an oral form is available in the case of XENLETA, adoption is not formulary dependent and can begin immediately by ED physicians, internists, and pulmonologists for their pneumonia or even suspected pneumonia patients.”

Contraindications include patients with known hypersensitivity to XENLETA or pleuromutilin and XENLETA tablets are contraindicated for use with CYP3A4 substrates that prolong the QT interval. Warnings and cautions state that the drug has the potential to prolong the QT interval and should not be used in patients with known QT prolongation, ventricular arrhythmias, or who are taking drugs that may prolong the QT interval.

“CYP3A is a route of metabolizing the drug, and other drugs share that same metabolism,” Lavino explains. “So you can be taking an inducer which would render XENLETA less effective, or you could be taking an inhibitor, in which case you have more drug in the blood. The label is clear on warning against concomitant use of inducers or inhibitors of this metabolic pathway”

The FDA granted approval of both the oral and IV form of XENLETA via their Qualified Infectious Disease Product (QIDP) and Fast Track designations. The QIDP guidance is designed to encourage the development of new antibiotics to address the growing microbial resistance problems in treating disease.
Medicare patients:

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Managing Autoimmune Diseases

The Pharmacist’s Role

Celiac disease, lupus, and the pharmacist.

By Jennifer Gershman, PharmD, CPh, contributing writer

There are over 80 different autoimmune diseases that impact the some 50 million Americans who live with one of those diseases. The causes of many autoimmune diseases are unknown, but genetics, infections, and the environment may play a part. Unfortunately, there is generally no cure for autoimmune diseases; however, there are medications and lifestyle modifications that can help to manage the conditions. Pharmacists can play an important role through an interdisciplinary approach in managing patients with autoimmune diseases. This article will focus on two common autoimmune diseases and what pharmacists need to know about them: celiac disease and systemic lupus erythematosus (SLE).

Celiac Disease Management, Counseling Points, and Treatments on the Horizon

Celiac disease is an immune reaction, in the form of gastrointestinal (GI) symptoms, to eating gluten. There are different theories regarding the cause of celiac disease, which include genetics, GI infections, and stress; however, the exact cause is unknown. Approximately 1 in 100 individuals are diagnosed with celiac disease globally, and about 2.5 million Americans are undiagnosed, which can ultimately lead to long-term complications.

GI symptoms may include: diarrhea, weight loss, bloating and gas, abdominal pain, nausea and vomiting, and constipation. Celiac disease can also cause various non-GI symptoms, including: anemia, osteoporosis, skin rash, mouth ulcers, headaches, fatigue, nervous system problems, joint pain, and altered spleen function. Serology and genetic blood testing along with an endoscopy can help to diagnose celiac disease.

The gold standard for managing celiac disease is adhering to a gluten-free diet, as chronic inflammation can cause damage to the inner lining of the small intestine. Gluten is a protein found in wheat, barley, and rye. Additionally, the FDA specifies that food carrying “gluten-free” labels must contain less than 20 parts per million of gluten. However, even trace amounts of gluten can cause GI issues.

Pharmacists can play an important role in guiding patients to select appropriate gluten-free foods and medications. Educate patients to always read product packaging to ensure they are labeled as gluten-free or have no gluten-containing ingredients (Table). Patients may have questions about whether their medications contain gluten. Most drug products contain gluten-free starches (e.g., corn, potato, rice).

Medications won’t usually advertise the word gluten, so it’s important to focus on the ingredients which can be found through the product information on sites such as DailyMed, Gluten Free Drugs, or Pillbox. The drug manufacturer can also be contacted for additional information. If gluten is contained in an oral drug product, the amount is generally less than 0.5 mg per unit dose, which is considered less than a serving of gluten-free food.

Patients with celiac disease may require vitamin and mineral supplements (e.g., iron) if anemia or other nutritional deficiencies occur. Medications may be used to alleviate inflammation, which include steroids (e.g., budesonide) and immunosuppressive drugs (e.g., azathioprine). Dapsone may be used to treat the skin rash dermatitis herpetiformis, which can occur in patients with celiac disease. Pharmacists can educate patients that frequent blood tests are needed while receiving treatment with dapsone and immunosuppressive medications to monitor for adverse effects.

According to a study published in the Journal of Pediatrics, use of text messaging was an effective intervention to improve patients’ quality of life, ability to manage their condition, work with healthcare providers, and prevent disease exacerbation. This may offer an effective technique for pharmacists and other members of the healthcare team to monitor diet adherence in patients with celiac disease.

There are currently no FDA-approved
medication treatments for celiac disease. However, there is a promising drug in the pipeline, larazotide acetate, that has received fast track designation and belongs to a new class of drugs known as tight junction regulators. Larazotide works by decreasing inflammation in the intestine triggered by gluten, and it is currently in a phase 3 trial that is expected to enroll about 600 patients.

SLE Management and Pipeline Drugs

According to the Lupus Foundation of America, approximately 5 million people globally are affected by lupus and about 16,000 new cases are reported annually. Lupus occurs when the body’s immune system attacks the tissues and organs, which can affect various body systems. Diagnosis is determined through a multifaceted approach with the combination of blood and urine tests, signs and symptoms, and physical examination. Symptoms generally include fatigue, fever, joint pain, photosensitivity, and a butterfly-shaped rash. Systemic lupus erythematosus (SLE) is the most common form of the four types of lupus.

According to a study published in *Arthritis Research & Therapy*, transitional care improved self-care and quality of life in SLE patients and reduced hospital readmissions. Pharmacists can play an important role in managing chronic medications for patients with SLE. NSAIDs, such as naproxen and ibuprofen, may be used for pain and swelling associated with SLE. Counseling points include an increased risk of cardiovascular and kidney adverse effects as well as stomach ulcers, which can occur even on short-term therapy with NSAIDs.

Hydroxychloroquine, the antimalarial drug, is commonly prescribed to decrease lupus flares. Side effects may include GI issues and damage to the retina, so it should be taken with food and patients should see an ophthalmologist prior to starting hydroxychloroquine.

Corticosteroids (e.g., prednisone) may be used to reduce inflammation, and adverse effects may include weight gain, osteoporosis, hypertension, diabetes, glaucoma, and increased risk of infection. Immunosuppressants such as azathioprine and mycophenolate mofetil are also used for severe SLE cases, and potential adverse effects may include infection risk, liver damage, decreased fertility, and an increased risk of cancer.

The biologic belimumab (Benlysta) was approved in 2011 for SLE in adults and received approval April 2019 as the first treatment for SLE in pediatric patients. The most common side effects associated with Benlysta include nausea, diarrhea, fever, and infusion reactions. Pharmacists should recommend that patients receive an antihistamine prior to Benlysta infusions to prevent a reaction.

Adrijana Kekic, PharmD, BCACP, Pharmacogenomics Pharmacist at the Mayo Clinic College of Medicine and Science, Phoenix, AZ, uses pharmacogenomics testing when making medication recommendations for patients with SLE with a personalized medicine approach. One example Kekic provided was thiopurine methyltransferase (TPMT) genotyping prior to initiating treatment with azathioprine, which facilitates identifying patients who are at increased risk for toxicity. Kekic also provides counseling tips as part of her patient consultations. “I recommend exercise and stress reduction for my SLE patients,” says Kekic, which can help improve energy and decrease lupus flares.

There are various drugs in the pipeline for SLE in phase 3 clinical trials, according to Kekic. Baricitinib (Olumiant) is FDA approved for rheumatoid arthritis and has been granted fast track status for the treatment of SLE.

One promising therapy rigerimod (Lupuzor), a novel biologic, failed to meet the primary endpoint in a phase 3 study based on clinical trial results reported in 2018. However, rigerimod met the primary objective of the open label extension study evaluating the safety and tolerability of the drug in patients with SLE, demonstrating no serious adverse effects in 62 patients. However, further studies are necessary with a larger number of study participants to determine the rigerimod’s fate.

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Packaged Foods that may contain gluten

<table>
<thead>
<tr>
<th>Soup</th>
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<tbody>
<tr>
<td>Candy</td>
</tr>
<tr>
<td>Gravies</td>
</tr>
<tr>
<td>Rice mixes</td>
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<tr>
<td>Processed lunch meats</td>
</tr>
<tr>
<td>Cereals, pasta, baked goods</td>
</tr>
<tr>
<td>Salad dressings and sauces</td>
</tr>
<tr>
<td>Beers, lagers, ales, malt vinegar</td>
</tr>
<tr>
<td>Seasoned snack foods (e.g., tortilla and potato chips)</td>
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**Kekic**
Pharmacy-based PrEP Clinics

An opportunity to dismantle barriers and combat an epidemic.

By John Schieszer

Pharmacists are well-positioned in the community to help educate patients and prevent new HIV infections; new state laws allowing pharmacies to set up pre-exposure prophylaxis (PrEP) clinics will determine the size of their role.

PrEP offers an effective means of protection for individuals testing negative for HIV; the FDA has approved the drug combination of 300 mg tenofovir and 200 mg emtricitabine sold under the name Truvada by Gilead Sciences. Emtricitabine 200 mg and tenofovir alafenamide 25 mg tablets are also under consideration by the FDA.

The list price of Truvada is $1,758 per month when taken daily; however, another alternative being proposed is the “2-1-1” approach. Instead of a daily pill taken indefinitely, an individual would take just 4 pills (2 pills within 2 to 24 hours before sex and 1 pill on day 2 and 1 pill on day 3). It is theorized that this type of PrEP regimen may be more convenient, cheaper, and elicit fewer side effects. So far, it reportedly has only been tested in men having sex with men and it has not been tested in women.

PrEP plays an important role in addressing the HIV epidemic, says Lindsey Dawson, associate director of HIV Policy at the Kaiser Family Foundation, Washington, DC. When taken daily, it reduces the risk of HIV acquisition through sex by about 99%. Dawson says for this reason it is included in the federal government’s plan to “End the HIV Epidemic.” However, only an estimated 10% to 20% of individuals in the U.S. who have an indication for PrEP have received a prescription. “Disparities are significant, particularly among African Americans and Latinos, as well as among people living in the south. To the extent that PrEP provision in the pharmacy setting increases PrEP uptake and improves adherence, this could play a meaningful role in reducing new HIV infections,” says Dawson.

Paul Weidle, PharmD, MPH, a senior epidemiologist at the CDC’s Division of HIV/AIDS Prevention, Atlanta, GA, says the CDC is currently looking into ways pharmacists can support “Ending the HIV Epidemic”, including efforts to increase PrEP uptake. “There are very encouraging examples of where pharmacists have addressed challenges to be able to provide support for PrEP delivery, either directly as providers or under collaborative practice agreements. These challenges must be addressed more fully in order for pharmacists to develop and implement strategies that will improve PrEP uptake,” Weidle tells Drug Topics.

“It is hard to say how many pharmacists will begin prescribing PrEP, either by running specific PrEP clinics or offering PrEP in pharmacies with existing co-located clinical facilities,” Dawson says. “Offering PrEP in pharmacy settings could increase patients’ ability to access this highly effective preventive medication.”

Addressing Barriers

Dawson says PrEP uptake is relatively low among certain groups, including gay and bisexual African American men; diversifying the locations and types of providers offering PrEP could be one way to address some of the existing barriers. “Pharmacists with the appropriate clinical facilities willing to offer PrEP are well-positioned providers, and the CDC guidelines offers clear direction on the clinical services and straightforward counseling that should be offered,” says Dawson.

“Physicians typically see their patients a few times per year; pharmacists see them monthly and often times several times per month. We are much more accessible, as patients only need to walk through the door and ask to speak to a pharmacist in most pharmacies,” Clint Hopkins, PharmD, owner of Pucci’s Pharmacy in Sacramento, CA, tells Drug Topics. He says this higher pharmacist-patient interaction frequency and easier access means more opportunity for pharmacists to discuss sexual health, risk factors, offer testing, and initiate PrEP. “Our greatest barrier is getting the patient’s insurance to pay for point-of-care testing. Many patients who are high-risk for HIV are also not financially situated to be able to pay for their own testing. Grant programs are one option that we are pursuing to get testing covered when patients are unable to pay.”

Glen Pietrandoni, senior director for patient care and advocacy for Walgreens pharmacies, says, as the most accessible healthcare providers in the nation, pharmacists can play a significant role in the care and prevention of HIV. “Walgreens has supported people living with HIV/AIDS since the beginning of the epidemic,” says Pietrandoni. “With more than 3,000 HIV-trained pharmacists in communities across the nation, we can uniquely support HIV prevention,
education, and care."

According to Pietrandoni, Walgreens pharmacists support patients with medication counseling and information on effective HIV prevention methods including PrEP. He says the option for pharmacists to prescribe PrEP and conduct related tests is a very important issue in the war on HIV. "Walgreens supports lowering hurdles for patients to access effective prevention options and is in favor of expanding the scope of services pharmacists can provide. Preventing new infections and keeping HIV positive patients virally suppressed are both critical strategies to prevent the spread of the virus and ultimately help eradicate it entirely," says Pietrandoni.

Two current pharmacy-based PrEP clinics in the U.S. are Kelley-Ross Clinic in Seattle and Mission Wellness in San Francisco. Washington State has passed legislation that requires insurance providers to cover point-of-care testing provided by pharmacists. San Francisco is operating on a grant in cooperation with SF General Hospital. "There is no question that state laws can enhance access to PrEP in non-traditional settings or can create barriers," says Dawson.

She says a law that address insurance coverage of lab testing in pharmacies is one example of a policy that could remove an important barrier to PrEP. This would help address affordability and reimbursement of PrEP-related services. "Another example of policy that would have an impact on PrEP in the pharmacy setting is pharmacist scope of practice laws. These differ from state to state and could either limit or expand access depending on their content," says Dawson.

Attempts to expand PrEP provision through pharmacies will need to consider several factors, such as pharmacist buy-in and education, reimbursement policies, and pharmacy infrastructure (i.e. access to lab testing), she says. The Kelley-Ross pharmacy in Seattle provides direct PrEP delivery and clinic operates under a collaborative drug therapy agreement that allows pharmacists to initiate and manage tenofovir disoproxil fumarate/entecavir under the supervision of a physician medical director.

This pharmacist-managed PrEP clinic has been found to be a successful alternative model of PrEP care—a study conducted by pharmacists at the clinic found that its model provided high initiation rates and good compliance. The pharmacists evaluated 714 patients, 695 (97.3%) of whom initiated PrEP and 513 patients (74%) patients who began medication the same day as their initial appointment. The mean age at initiation of treatment was 34.7 years. The researchers found that among those patients who filled their prescription, 90% had a mean proportion of days covered (PDC) greater than 80%. There were no HIV seroconversions, but there were 207 diagnoses of sexually transmissible infections (mainly chlamydia and gonorrhea cases).

Hopkins says a PrEP clinic can be a source of revenue, but how well enlisted pharmacists are in combating the HIV epidemic will be determined by state laws and reimbursement policies. "New HIV infections are still occurring in an era where we have a prevention method that the general population either isn’t educated about or do not have adequate access to obtain. We want to reduce the number of new HIV infections to zero by getting everyone who is at risk tested and those interested and eligible on prevention medication."
Flu Season
What you should expect from the 2019-2020 flu season.

By Kayt Sukel

Earlier this summer, the CDC rated the 2018-2019 influenza season, coming in two distinct waves and lasting 21 weeks, as “moderately severe.” The report concluded that influenza A viruses dominated two waves of the season, while influenza B showed only minimal activity. But while many are still conducting an after-action review of last year’s flu season, many physicians and pharmacists are concerned about what the year ahead may bring.

To that end, the CDC recently published its predictions about the upcoming season in a report entitled, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2019–20 Influenza Season. The agency also updated its public webpage regarding the upcoming 2019-2020 flu season.

The public health agency notes that the latest trivalent, or three-component, flu vaccine will protect against three distinct strains that experts expect to be most common this year: they include the A/Brisbane/02/2018 (H1N1)pdm09-like virus, A/Kansas/14/2017 (H3N2)-like virus, and B/Colorado/06/2017-like (Victoria lineage) virus. The quadrivalent vaccine will have the addition of the B/Phuket/3073/2013-like virus of Yamagata lineage.

**Are Flu Vaccines Still Worth it?**
The report also provides updated dosing and age recommendations for certain vaccines like the Afluria Quadrivalent and Fluzone Quadrivalent. Aaron Glatt, MD, FACP, FIDSA, FSHEA, chair of medicine at South Nassau Communities Hospital and a spokesperson for the Infectious Disease Society of America, says he doesn’t think there were any real surprises in the report.

“Their guidelines are very similar to what we’ve seen in previous years,” he said. “They are solid and appropriate. That said, it’s too early to tell whether the vaccine is a good match for the upcoming season. We won’t know that until we see what kind of cases are being reported and what strains are actually out there resulting in severe illness.”

That said, despite some reports of last year’s vaccine being a bad match (according the CDC, the vaccine was just 29% effective overall), Glatt says it is imperative that clinicians and pharmacists educate patients that even a poorly matched vaccine still offers important protection not just to individuals, but to society at large.

“Being vaccinated helps you avoid being infected with the disease. And if you do catch the flu, it will lessen the severity of the symptoms,” he explains. “Patients should also know that last year’s vaccination, even if it wasn’t the best match, remains protective. Research shows that people who are vaccinated for the flu every year have an advantage over those who aren’t vaccinated or even have just gotten their first vaccine this year.”

He suggests that pharmacists take the time to disabuse patients of common myths regarding the flu shot.

“One of the biggest myths people have is that they can get the flu from the flu shot. That’s just not true. It is essentially impossible to get the flu from the flu shot. If you happen to get the flu about two weeks after the flu shot, it was just a coincidence. There’s a small number of patients who might have mild discomfort after the shot but it’s nothing like getting the actual flu,” he says. “The other area where pharmacists can help promote vaccinations is by explaining that even a so-called bad match vaccination still helps to prevent serious illness.”

He adds that pharmacists who are looking to help improve vaccination numbers should look to the bigger box pharmacies like CVS and Walmart for guidance.

“They know how to do it,” he said. “They make it really easy for a person to just get the vaccine. No appointment, no waiting—they advertise with big signs and can answer questions and then do it right on the spot. Pharmacists have an important role to play, and I think physicians would like them to do more, to see more patients getting vaccinated each year as early in the season as possible.”
5 Types of Diabetes Patients Who Need More Management

By Tzipora R. Lieder, RPh, contributing writer

With over 23 million Americans diagnosed with diabetes, chances are some of them step through the door of your pharmacy every day.

“Every patient who has diabetes needs counseling, whether they’re picking up a brand-new prescription or getting a refill on an existing prescription,” stresses Susan Cornell, PharmD, CDE, associate director of experiential education and associate professor of pharmacy practice at Midwestern University Chicago College of Pharmacy in Downers Grove, IL. For every prescription they dispense, Cornell says, pharmacists should ensure the patient understands what it’s for, how to take it, and how to minimize side effects.

But some patients with diabetes need more in-depth education about their disease and its treatment. In the busy retail environment, how can pharmacists determine who these patients are?

1 Self-Reporting Numbers Out of Range (Or Failing to Test)

Whenever a patient picks up a diabetes prescription, Cornell says, the important question to ask is “So what was your blood sugar this morning?” This simple question, she says, helps gauge the patient’s understanding of his condition and whether more education is needed.

If the patient’s answer indicates that her blood glucose is elevated, Cornell recommends following up with “What does that mean to you? What is your goal? How often are you getting numbers that are above your goal?” These questions can springboard a discussion about how the patient can better reach her goals.

On the other hand, if the patient responds, “I didn’t check my blood sugar,” the pharmacist should ask why not and then discuss the crucial role of testing to gain information about how well the patient’s drugs, diet, and exercise are working.

For patients who mention frequent hypoglycemic episodes, the pharmacist can help investigate the cause. Cornell says, “What time of day does hypoglycemia typically occur? Is the patient skipping meals or exercising without replenishing nutrients?”

2 Newly Diagnosed or Starting Insulin Therapy

Travis Wolff, PharmD, BCACP, co-owner of Med-World Pharmacy in Sapulpa, OK bases his recommendations for pharmacist diabetes education on the critical times for diabetes self-management education and support (DSMES) identified by the American Diabetes Association (ADA; see Table 1).

Patients coming in for the first time with a prescription for an antidiabetic drug (typically metformin for type 2 diabetes) are overwhelmed, says Wolff. He adds that he doesn’t want to overload them with information, so he advises giving them a “survival level education.” These patients are often confused by all the different blood glucose numbers they’ve heard mentioned, Wolff notes, so they need clear information about fasting and 2-hour postprandial blood glucose goals.

Patients must be prepared to handle episodes of hypoglycemia, he says, particularly if they are being treated with insulin, “Make sure they know to drink non-diary soda or have non-sugar free candy!” Wolff notes. For patients beginning to use a glucometer, he recommends a 15-minute training session to teach them how to use it properly so they can be comfortable and independent with the meter.

3 New Non-Diabetes Prescriptions

While new prescriptions may seem to be unrelated to diabetes, vigilant pharmacists may realize that patients’ new conditions may be associated with microvascular or macrovascular complications of diabetes, Wolff says. Examples include prescriptions for nerve pain, ophthalmic issues, gastrointestinal issues, anticholesterol drugs, and even levothyroxine. “It’s a great opportunity to get involved and help them,” Wolff says, “because if they are getting more complications then their diabetes is probably not as well controlled as it could be.” The way to open this conversation is to go back to square one, says Wolff, with a question like, “What are your blood sugars running?”

4 Type 1 Diabetes Transitioning to Adulthood

While we typically think of transitions as those involving health care institutions,
such as assisted living to nursing home, hospital to rehab center, or the like, Wolff points out that there are many significant transitions occurring outside the institutional environment that provide key opportunities for education. Chief among them is the transition to adulthood for an individual who was diagnosed with type 1 diabetes during childhood. Eighteen-year-olds with diabetes going off to college or work need education about how to manage their diabetes, Wolff says. “They are no longer under the supervision of Mom and Dad where they had their diet controlled, constant reminders to take their medication, and constant reminders to keep them healthy in every way,” he explains. Education can empower these young adults to take charge of their own diabetes.

Switching to Medicare

The transition to Medicare at age 65 can be very significant transition for patients with diabetes, Wolff says. “They might have to go somewhere else to get their test strips,” he says, “or they may have to change diabetes drugs due to formularies, which is a really big deal.” He sees many patients who need to switch between insulin products for this reason and require education about the new product.

Wolff says that even switching to a new Medicare plan each January comes with many questions. “It’s important that they come to the community pharmacist to help them understand whether the medications that are currently on will be covered under new plan for next year,” Wolff notes. “They have to see if they’re willing to switch to the new formulary agents or switch plans to one where it is covered.”

Have the Discussion

Educational conversations with diabetes patients are often patient-led, Wolff says, but questions are an important part of eliciting the patient’s involvement. Wolff recommends basing questions on the American Association of Diabetes Educators (AADE)’s seven self-care behaviors of diabetes (sidebar), such as “How has your diet been lately? How has your physical activity been? Have you been taking your medicine regularly?” To help with workflow in busy pharmacies, Wolff recommends training pharmacy technicians and clerks to ask these sorts of questions to patients with diabetes so they can identify those that need a more in-depth conversation with the pharmacist. While pharmacy technicians are not permitted to counsel in most states, they may ask questions, Wolff explains. “The minute the patient has a question back or the patient doesn’t answer the question in the appropriate way, it’s time to get a pharmacist involved.”

Wolff stresses teaching patients how to incorporate diabetes management into regular life. Remind patients that exercise doesn’t only mean walking on a treadmill; physical activity can be incorporated into routines by parking further from the store or carrying shopping bags to the car. Broaching these topics is valuable, he says. “Just the fact that you’re asking the questions makes them subconsciously eat better and take care of themselves.”

When More Education is Needed

It’s important for pharmacists to know their limitations, Cornell says, and to refer patients to other resources when necessary. Just as primary care physicians have referral lists, Cornell believes that every pharmacist should have a referral list. “We should have a diabetes education program we can refer a patient to, a dietitian who specializes in diabetes, an endocrinologist, a podiatrist, a dentist where we know our patient is going to get the proper care,” she says.

4 CRITICAL TIME POINTS
FOR PROVIDING DSMES

1. At diagnosis
2. Annually
3. When complicating factors occur
4. During transitions of care

Source: ADA and AADE

AADE’s 7 Self-care Behaviors for Diabetes

- Healthy Eating
- Being Active
- Monitoring
- Taking Medication
- Problem Solving
- Reducing Risk
- Healthy Coping
Drug Shortages Continue to Burden Healthcare

How PBMs can anticipate and manage drugs in short supply. By Mari Edlin

Although the number of new drug shortages in the United States has declined to 186 in 2018 since a high of 267 in 2011, there have been 80 for the first half of 2019, according to the University of Utah Drug Information service.

“Shortages continue to be on the rise and in talking with our customers, we’ve discovered the problem continues to get worse. More medications are going on allocation or unavailable and what used to be short, periodic shortages have become long and drawn out, making it a continuous challenge for clinical leaders,” says Patrick Yoder, PharmD, CEO, LogicStream Health, a Minneapolis-based clinical process improvement and control software provider.

“Some medication shortages have been going on for years with no real sign of recovery,” he says.

“While the number of drug shortages has declined substantially in recent years, any drug shortage places substantial burdens on healthcare, providers who may have to ration medicines or identify alternative treatments,” says Andrew Powaleny, director, public affairs for Pharmaceutical Research and Manufacturers of America (PhRMA).

“The issue of drug shortages demands attention and collaboration from all stakeholders involved in providing life-saving medicines to patients. This includes the biopharmaceutical companies producing brand-name medications, as well as generic drug and biosimilar manufacturers, wholesalers, distributors, pharmacies, and healthcare providers,” he says.

A survey conducted between March 6 and April 4, 2019 of 365 acute and non-acute care facilities across the country—members of Vizient, a healthcare performance improvement company headquartered in Irving, Texas—confirms the ever-present problem of drug shortages and their ramifications.

Nearly two-thirds of respondents report they managed at least 20 shortages from July through December 2018; 64%, more than 21; 33%, six to 20; and 3%, up to five. Thirty-eight percent report one or more medication errors directly related to a drug shortage in that same time period.

The most commonly reported items facing shortages, according to the survey, are controlled substances, local anesthetics, antibiotics, electrolytes, and emergency injectables such as “crash cart” drugs, many of which are low-cost generics.

Injectables comprise 39% of drug shortages in 2019, according to the University of Utah Drug Information Service.

Top causes of drug shortages

The FDA primarily attributes shortages to quality/manufacturing issues but also points to production delays, some caused by not receiving raw materials and components from suppliers, and drug discontinuations. An estimated 70% of shortages are caused by manufacturing and quality problems, according to the Healthcare Supply Chain Association.

“The FDA can’t require a firm to keep making a drug it wants to discontinue. Sometimes these older drugs are discontinued by companies in favor of newer, more profitable drugs,” says Charlie Kohler, spokesperson for the FDA. “With fewer firms making older, sterile injectable drugs, there is a limited number of production lines that can make these drugs. Raw material suppliers also are limited in the amount they can make due to capacity issues at their facilities.”

Kohler says that these limitations, along with long lead times and the complexity of the manufacturing process for injectable drugs, result in shortage vulnerabilities. “When one company has a problem or discontinues, it is difficult for remaining manufacturers to increase production quickly, and a shortage occurs,” he says.

Dan Kistner, PharmD, senior vice president, pharmacy solutions for Vizient, outlines the causes of drug shortages:

› Supply chain unavailability
› Lack of active pharmacy ingredients
› Natural disasters
› Too many lines offered, making it difficult to maintain capacity
› Regulatory issues
› Aggregate product quota preventing other manufacturers who might enter the space from making more product
› Low ROI. If a product is not profitable, manufacturers might switch to other drugs
› Consolidation

Powaleny attributes drug shortages to shifts in clinical practices; wholesaler and pharmacy inventory operations; changes in hospital and pharmacy contractual relationships with suppliers.
and wholesalers; and manufacturing issues, such as an unforeseen breakdown in manufacturing equipment that disrupts production.

“The difficulty is identifying what medications will be impacted by any of these things and how that will affect care delivery and patient safety, along with understanding when any particular shortage will occur,” Yoder says.

**Shortages create repercussions**

“The biggest risk is patient safety and potential harm to patients when clinicians cannot deliver appropriate care because of a medication shortage. Defering procedures, adverse drug events, medication errors, cost of alternatives, and the time clinical teams spend managing shortages are all results of shortages,” Yoder says.

The Vizient survey focuses on the impact of drug shortages on U.S. hospital labor forces. Responses indicate that shortages are costing these institutions $359 million a year in labor expenses, or about 8.6 million hours of additional labor, to seek supply, update technology, and implement mitigation strategies that enable continuity of care. Survey participants attributed labor costs to triaging patients and making changes in the ordering system.

The repercussions of drug shortages not only impinge on financial resources but also on patient care, from delay or cancellation of a medication or treatment to medication errors. The Institute for Safe Medication Practices conducted a survey primarily of hospital-based pharmacy directors and managers, purchasing agents, and technicians from August through October 2017. It found that the majority (71%) were unable to provide patients with a recommended drug or treatment, and 47% thought this resulted in patients receiving a less effective drug. In addition, 75% stated that patient treatments had been delayed because of drug shortages.

**Solving the drug shortage problem**

Kistner recommends some strategies for mitigating drug shortages: increase competition; ramp up supply and capacity; reward quality in generics; expedite manufacturer approval processes; provide real-time analytics about what is purchased and which supplies are dwindling; and apprise hospitals of potential drug shortages so that they do not become a repeat problem.

Among Vizient’s solutions are Novaplus, which provides access to 15,000 individual, high-demand line items encompassing a broad range of categories. Respondents to the Vizient survey had a say in what they believe to be effective solutions to the drug shortage problem: implementing processes to restrict duration of therapy; increasing stock of medications that were anticipated to be limited in supply; utilizing unit dosing to prevent waste; using alternative ways of administering a drug; and implementing one or more taskforces or committees dedicated to addressing drug shortages and allocations.

LogicStream has introduced the Drug Shortage App that identifies shortages and their impact on hospitals and automates the entire life cycle of managing a shortage. It provides clinical information that allows teams to understand and mitigate the ramifications for shortened medications. Yoder says that although most hospitals have a drug shortage management process, they tend to be manual, time-consuming, and costly.

**FDA tackles drug shortages**

“FDA responds to potential drug shortages by taking actions to address their underlying causes and to enhance product availability. It determines how best to address each shortage situation based on its cause and public health risk,” Kohler says.

To address manufacturing/quality problems, FDA works with manufacturers to resolve issues, from an incorrect expiration date on a package to finding a particulate in a product. “Regulatory discretion may be employed to address shortages to mitigate any significant risk to patients,” he says.

The agency also assists manufacturers with drug shortages in ramping up production if they are willing to do so. Kohler says this often necessitates approval of new production lines and raw material sources to help increase supplies. FDA expedites review of these to help resolve shortages of medically necessary drugs; however, the agency can’t require companies to increase production.

If a manufacturer has data to support extension of an expiration date for inventory that is close to expiration or has already expired, FDA is able to review this information and approve the extension, helping to increase supplies until new production is available.

In addition, FDA could turn to other manufacturers that are willing and able to redirect product to the U.S. market if a shortage involves critical drugs needed for U.S. patients. This requires an evaluation of a product to ensure efficacy and safety, including the formulation and other attributes of a drug and the quality of the manufacturing site where a drug is made.

Kohler says that while the FDA looks for ways to mitigate drug shortages, there are a number of factors that can cause or contribute to the problem that are outside of the FDA’s control.

The agency issued a long-term, strategic plan to outline its priority actions and efforts drug manufacturers and others can take to prevent drug shortages by promoting and sustaining quality manufacturing, along with launching the Drug Shortages Task Force July 2018, to study reasons why shortages continue.

Mari Edlin is a frequent contributor to Managed Healthcare Executive, in which this article first appeared.
By Kayt Sukel

Earlier this month, Judge Richard Leon of the United States District Court in Washington completed his review of the United States Justice Department’s decision to permit CVS Health, the owner of the largest pharmacy chain and one of the largest pharmacy benefit managers (PBMs), and Aetna, a leading American health insurer, to merge, determining that the agreement did not violate antitrust law.

While many in the healthcare industry had voiced concerns that the merger would hurt competition, particularly affecting independent pharmacies, Aetna agreed to sell its Medicare prescription drug plan business to WellCare Health Plans in order to further open up the market. In granting the motion, Judge Leon stated that, “CVS and the government’s witnesses, when combined with the exiting record, persuasively support why the markets at issue are not only very competitive today, but are likely to remain so post-merger.”

But Kamaljit Behera, a transformational health senior industry analyst with Frost & Sullivan, a global market research and analysis firm, says critics’ concerns of the merger are not without merit. With this agreement now in place, CVS has no real incentive to keep drug prices lower for insurers who are competing with Aetna, especially as WellCare continues to rely on CVS for pharmacy benefit management and retail pharmacy services. And it’s not clear that Centene’s decision to acquire WellCare for $15.27 billion, which many hoped would reduce potential antitrust issues, will offset those issues.

“We are seeing further centralization of power,” he said. “Today, five PBMs control more than 85% of the market and the top five pharmacies have more than 40% of the retail market share. This centralization of power without enforcement of transparency in margins and rebates is one of the reasons for the ambiguous and high drug pricing in the United States.”

Since November 2018, the industry has carefully followed CVS’ transformation from a pharmacy chain to a more all-encompassing health services company. CVS has added additional primary health services at its MinuteClinics as well as expanded its virtual care options for patients with chronic health conditions. In addition, it has availed itself of Aetna’s vast trove of data in order help identify the right locations for future clinics and HealthHUBs. The company also plans to open 1500 more HealthHUBs—which provide health services right in its pharmacy retail stores—by 2021. Taken together, these moves show the kind of market power CVS’ and Aetna’s consolidation has brought to bear.

While the deal had not officially gone through until this latest review, CVS and Aetna were already essentially operating as a single entity—a fact that did not go unnoticed by Judge Leon, who took a moment to chastise the very common practice of companies acting as if merger deals were closed while the decision remained under court review, as required by the Antitrust Procedures and Penalties Act, better known as the Tunney Act.

“If the Tunney Act is to mean anything, it surely must mean that no court should rubber-stamp a consent decree approving the merger of one of the largest companies in the United States’ and ‘the nation’s third-largest health-insurance company; simply because the government requests it.’”

What will the end result be? Khusbu Jain, a transformation health industry analyst, also at Frost & Sullivan, says CVS’s enhanced reach in the healthcare industry may offer greater convenience to consumers—but it likely won’t translate into what patients most want to see: lower healthcare or drug costs.

“The industry is already heavily consolidated,” she explains. “Cigna announced its acquisition of Express Scripts in March, soon after the CVS-Aetna news came out. And, in preparation for market headwinds and that concentration of power, companies are already looking at expanding their offerings in order to compete. For example, Anthem has now launched its own PBM, IngenioRx.”

She adds that in light of high drug prices as well as poor transparency regarding what drives those costs, drug price comparison websites and apps—such as BlinkHealth and RxRevu, as well as ePharmacy vendors like Amazon+PillPack—may end up the real winners in the long run from these large-scale mergers, as they can offer the savings consumers are seeking.

“Pharmacies, in general, will become the central cog in patient care and recovery and elevate their roles from being a commodity provider to an active participant in the patient care regimen,” she says. “Pharmaceutical companies will be in duress as the balance of power shifts—and price pressure increases from all sides.”
Excellent communication between pharmacists and other healthcare providers is key to providing the best patient care possible, and dentists are no exception.

While dentists may not be the most common healthcare professionals pharmacists work with, there are a few areas where collaboration is relatively common: allergies and opioids (see Table 1).

Communication Counts

Alan Tanabe, PharmD, Staff Pharmacist at Meijer in Ann Arbor, MI, feels that dentists and pharmacists can work well together. "Occasionally, I will come across a prescription issued for amoxicillin for a patient with a documented beta-lactam allergy, or a prescription for ibuprofen for a patient who is already taking another NSAID for a different reason, but these issues are usually resolved quickly with a call to the prescribing dentist," he said. He finds that most problems are quickly resolved as long as the issue is presented respectfully and backed by evidence-based information if needed.

Although it can be difficult to juggle these acute prescriptions with everything else happening in a busy chain, Tanabe says that "we will triage the needs of a patient, especially post-procedure."

In terms of opioid prescribing by dentists, Tanabe says that he has observed most dentists being very conscientious about keeping the number of opioids limited to what a patient will actually need.

Tanabe believes in the importance of “open communication and team-approach.”

Anne Henriksen, PharmD, pharmacist and owner at Malley’s Compounding Pharmacy in Richland, Washington, agrees that collaboration is key. "The profession of pharmacy always comes down to relationships. Although the scope of dentists may be very focused, treatments and medications that they prescribe can interact with other chronic medications the patient may take. Pharmacists are the medication therapy experts. Ensuring all prescribed medications are safe and appropriate for the patient through many different fields of practice is an essential part of the pharmacist’s responsibility," she says.

Building relationships is critical: “it is always difficult to truly understand another practitioner’s field of practice. Dentists who frequently use your pharmacy and speak with and have a relationship with a pharmacist will be more likely to be able to communicate appropriate expectations with their patient,” Henriksen says.

Henriksen has noticed a shift in prescribing in recent years. "For opioid-naïve patients who are having a simple dental procedure, ibuprofen and other NSAIDs have been shown to provide excellent pain relief," she says. "With the increased focus on addiction from prescription opioids, dentists are more conservative with prescribing painkillers."

When an issue arises with an allergy, drug interaction, or any other issue,
Antibiotic & Opioid Use

DENTAL ANTIBIOTIC COUNSELING

- It is always good practice to double check allergies to medications, especially when the patient is receiving an antibiotic.
- Remind patients to follow instructions, and to finish the course of antibiotics even if they are feeling better.
- Other counseling as specific to antibiotic—take with food, avoid sun, side effects, take with probiotic, etc.

DENTAL (SMALL QUANTITY) OPIOID COUNSELING

- Follow instructions from the dentist (ex: If the dentist says to try ibuprofen before Percocet, remind the patient to do so).
- No driving, no alcohol, no operating heavy machinery.
- Risk of addiction.
- Unlike antibiotics which are taken around the clock, opioids should only be taken as needed for severe pain.
- Keep out of the reach of children.
- Do not let leftover medication stay in the house—counsel patient how to discard safely.
- Counsel on concurrent benzodiazepine use, if applicable.

REFERENCE
Providing Healthcare to Transgender Patients

Education can help pharmacists feel more comfortable in dispensing care.

By Joan Vos MacDonald

About 1.4 million Americans identify as transgender (TG) or gender non-conforming. For many of these patients, pharmacotherapy is a part of their gender-affirming transition. Yet, research shows that transgender patients face significant barriers in obtaining healthcare, which can delay treatment and complicate existing conditions. Although pharmacists serve as an important link in providing necessary healthcare, many may not feel confident about dispensing care to transgender patients. Education is key.

The American Psychological Association defines transgender as “an umbrella term for persons whose gender identity, gender expression or behavior does not conform to that typically associated with the sex to which they were assigned at birth.”

“At birth, individuals are identified with a biological sex based on their reproductive organs, whereas gender identity refers to one’s self-identification of being a man or woman or non-binary (neither a man nor a woman),” says Cheyenne Newsome, PharmD, clinical assistant professor in the department of pharmacotherapy at Washington State University’s College of Pharmacy and Pharmaceutical Sciences. “Specifically, the term transgender is used to define people who identify with any gender that is different from their biological sex at birth.”

Already feeling at odds with a body that does not reflect their identity, transgender patients may face daunting difficulties accessing healthcare. A 2015 U.S. Transgender Survey reported that a third of all transgender individuals who had recently seen a healthcare professional experienced harassment, denial of care, or problems getting reimbursed by their health insurance. Fearing mistreatment, transgender patients may delay getting treatment when they are sick or injured or put off getting necessary preventive care.

Financial challenges may also be a factor, with 50% of transgender persons estimated to earn less than 100% of the federal poverty level and at least 33% being on Medicaid. The 2015 U.S. Transgender Survey found the unemployment rate among transgender individuals to be 15%, three times higher than the national average, which is likely due to discrimination based on their gender identity.

“Many transgender individuals who seek care do not believe that they can receive or afford adequate services for their health, yet they often have pressing health issues that are unresolved,” says Newsome.

According to Michael W. Jann, PharmD, professor of pharmacotherapy at University of Northern Texas System College of Pharmacy, a multi-disciplinary care model should include: primary care, family planning, medical procedures, HIV and STD care, medical subspecialties, behavioral health, speech therapy, dentistry, optometry, and community and clinical pharmacy services.

“Transition is a complex and individualized process to help the person transform their physical appearance to match their gender identity,” says Jann. “The time for maximal effects of antiandrogen and estrogen therapy may take as long as three years while testosterone treatments take five years with consistent usage.

Aside from the complex process of transition, transgender patients also need preventive services as well as treatment for various medical conditions. Hypertension, obesity, diabetes, heart disease, and dyslipidemia are also common medical conditions occurring with transgender persons and can be more complicated with long-term hormonal therapies.

Transgender patients also suffer disproportionately from conditions easily exacerbated by stress, such as asthma and gastrointestinal disorders. Due to the stigma and discrimination experienced by the transgender population—especially transgender youth—patients may also be more vulnerable to depression, anxiety, suicidal ideation, self-harm, STDs, alcohol and drug abuse and dependence.

“One of the most alarming statistics is the suicide attempt rate,” says Newsome. “Nearly half of all transgender people reported attempting suicide compared...
to 1.6% of the general population. This shows that the transgender community needs extra care, attention and support from healthcare providers to ensure we are meeting their healthcare needs and providing a safe environment for them to disclose their gender identity."

HIV is another problem compounded by a lack of access. The CDC reported that in 2017, the percentage of transgender people who received a new HIV diagnosis was three times the national average. Yet, nearly two thirds of transgender women and men surveyed by the Behavioral Risk Factor Surveillance System (BRFSS) in 2014 and 2015 never got tested for HIV. If they do get tested some patients may wonder about getting treated because the medication might interfere with hormone therapy.

**Current Systemic Problems**

"Healthcare systems can be challenging, where routine laboratory assessments can be difficult for TG persons as the forms typically include only a male or female designation," says Jann. "The laboratory interpretation can also be challenging (eg, hematocrit normal range). Electronic medical and pharmacy records may pose a problem as expanded identification beyond the male or female designation is necessary. Transgender persons may change their name, legal sex, and birth certificate, which can present problems in processing insurance claims.”

Anti-discrimination laws don’t always protect transgender patients. Several states have conscience or refusal laws that give pharmacists the right to refuse to perform services that they feel violate their religious or personal beliefs or values. Some of those laws incorporate patient protections, insisting that an objecting pharmacist seamlessly pass on the prescription to a fellow pharmacist who does not object; they may not obstruct the patient from getting a prescription.

In 2018, Hilde Hall, a transgender patient, tried to fill her first prescription for hormone therapy at her local CVS pharmacy in Fountain Hills, Arizona. In a statement to the American Civil Liberties Union, she related her excitement that day at starting therapy, but the pharmacist refused to fill her prescription. She also said he humiliated her, asking loudly, in front of other customers, why she was taking the prescription. Hall eventually filed a complaint with the Arizona State Board of Pharmacy.

By Arizona state law, a pharmacist cannot be terminated for refusing to fill a prescription that goes against personal religious beliefs; however, the pharmacist did not comply with CVS company policies, resulting in his termination. CVS apologized to Hall for the way she was treated.

“The conduct of the pharmacist, who is no longer employed by CVS, violated company policies and did not reflect our values or our commitment to inclusion, non-discrimination and the delivery of outstanding patient care,” says Mike DeAngelis, senior director of CVS Corporate Communications.

Since then, CVS pharmacists have been directly involved in the development of a resource guide for providing pharmacy care and services to LGBTQ patients for the Human Rights Campaign (HRC). The guide provides information on LGBTQ identities and terminology, as well as the unique needs of LGBTQ patients.

“We are very proud to have earned a perfect score on the Human Rights Campaign’s Corporate Equality Index for the past four consecutive years for our policies and practices related to LGBTQ equality,” says DeAngelis.

The chance to consult with a professional, non-judgmental pharmacist tends to improve adherence for any patient’s treatment, yet many pharmacists who would like to help transgender patients feel unprepared to do so.

“In a recent survey of pharmacists, 83% agreed that pharmacists play an important role in TG healthcare, but only 36% reported confidence to treat TG persons,” says Jann. “Further, 71% of the respondents reported not being educated about TG persons in their pharmacy education. A recent pharmacist’s survey reported that 52% rated their competency to treat TG persons as “very little” or “not at all” while only 15% stated “a lot.”

Alexander Gilmer, PharmD, a clinical pharmacist at New Hanover Medical Center in Wilmington, North Carolina, graduated pharmacy school in 2014. At that time, his education on transgender care was minimal.

“They basically said transgender people are out there and we use hormones with them,” Gilmer says. “There was nothing on how to interact with transgender patients or how to treat these patients with respect. As humans, we worry about accidentally disrespecting people and getting a negative reaction if we say the wrong thing. Without education, it’s this wild west frontier, there’s no idea what to do.”

**Improving Awareness & Education**

“GLAAD and The National Center for Transgender Equality each have some great resources to learn more about people who are transgender and how you can be an ally and support them,” says Newsome.

One way to make a pharmacy more gender affirming is to properly address transgender patients, to ask what name they like to use or their preferred pronouns. Addressing patients in the way that feels best to them demonstrates respect.

“You cannot know for certain by someone’s appearance what gender identity they have or what pronoun they use, so you must ask them,” says Newsome.
Pharmacies can also advertise that they are an ally.

“You can add additional signage or displays stating you are transgender or LGBTQ friendly,” says Newsome. “You can personally choose to wear a small emblem that displays a rainbow, inclusivity symbol, or the colors of the transgender flag.”

Ideally, community pharmacy and hospital settings should have gender-neutral bathroom facilities and private rooms for patient consultations.

“Transgender patients may not share their gender transition process or gender identity with all of their social circles due to fear of loss of social relationships, being fired from employment, or physical harm,” says Newsome.

According to Jann, pharmacy, like other healthcare providers, should lead and set an example for its professionals in providing inclusive and competent care for LGBTQ persons.

“Some states (eg New York Council of Health-System Pharmacists) have published a position statement supporting education on transgender patient care in pharmacy schools,” says Jann. “Professional education and professionalism are excellent initiatives taken by pharmacy schools and organizations. Further publications in pharmacy including pharmacotherapy, best practices, and research are needed.”

A recent survey of AACP-accredited pharmacy programs found that half of pharmacy schools addressed the needs of transgender patients in their curriculum.

“This is encouraging, but that also means that half of our pharmacy graduates have no training about the needs of transgender patients and how to provide quality care to them,” says Newsome, who teaches sessions on transgender care to three doctorate of pharmacy programs. “Many large pharmacy meetings have hosted sessions on pharmacists’ role in caring for patients who are transgender. There are webinars available specifically for pharmacists and transgender patient care is also making its way into pharmacy school curricula.”

According to Newsome, providing information on transgender terminology and health disparities as well as how to create a welcoming environment for transgender patients, and providing clinical information about hormone therapies for gender affirmation, definitely delivers results.

Newsome is the author of Addition of Care of Transgender-Related Patient Care into Doctorate of Pharmacy Curriculum: Implementation and Preliminary Evaluation, a study that documented the result of providing three hours of information about transgender healthcare to pharmacy students. Before the class, the median confidence level was 4/10; after the class, the confidence level had risen to 7/10.

Gilmer has also seen a positive response after teaching pharmacists about transgender care. Attending pharmacists said that as a result of the sessions they knew what to do and could more comfortably interact with their patients.

“It made them realize they can’t go into every prescription assuming they have all the info,” said Gilmer. “Maybe look a little further into the patient’s profile. Education can be as simple as learning what transgender people face, what it means to be transgender.”

Gilmer shared the story of a friend who opened a pharmacy that is slowly becoming a trusted resource for transgender patients.

“In a short time, she had her transgender patient population go from not having any cases to now having five or six cases,” says Gilmer. “What happened is that people are talking to other people in the community, saying this pharmacy is cool, it’s safe to go to. They are helpful and super respectful.”

Creating a warm and welcoming pharmacy essentially comes down to treating patients with respect.

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**The Human Rights Campaign offers guidelines on how to make a pharmacy more welcoming to transgender patients:**

1. **Educate staff on transgender issues and care, covering the correct terminology, the challenges transgender patients face, and some of their unique healthcare needs.**

2. **Create a welcoming environment with signs and literature targeted at the LGBTQ community.**

3. **Have a single-use gender-neutral bathroom for customers.**

4. **Never make assumptions about a person’s gender identity based on their name or the way they look.**

5. **Only use gender pronouns once you have established the patient’s identity.**

6. **Be aware that transgender patients are likely to have identification and insurance documents that do not accurately reflect their current identity.**

7. **Do not ask unnecessary or personal questions.”**
Contemplating the Future of List Prices

What experts think about the future of drug costs.

There’s no doubt: drug costs are skyrocketing—and those rising prices are affecting providers, payers, and patients in a variety of different ways.

According to a recent Kaiser Family Foundation research study, Medicare Part D enrollees without low income subsidies are looking at having to pay thousands of dollars out of pocket for single specialty drug this year. Such costs, especially with baby boomers retiring at an average of 10,000 people per day, are unsustainable—and President Donald Trump and others in government have been clamoring for ways to reduce list prices.

But as all eyes are on drug manufacturers to see how they respond to increased political and consumer pressure, Nitin Naik, Vice President of Global Life Sciences and Transformational Health at Frost & Sullivan, says there are many factors that are contributing to rising drug prices. He says current research and development efforts are, in fact, one of the main drivers behind the increasing price tags seen on drugs.

“There are several factors at play but mostly it’s the introduction of innovative molecules and specialty drugs used to treat complex disease pathways like oncology, rare disorders, and infections diseases like Hepatitis C,” he explains. “These all contributed to the overall increase in drug expenditures.”

Perry Cohen, PharmD, chief executive officer of the Pharmacy Group and the TPG family of companies, which provide services to associations, healthcare, and information technology organizations, payers, and pharmaceutical companies, says that the price increases of existing specialty drugs, sales, and marketing activities tailored to providers and patients to drive demand for specialty drugs, the lag in biosimilar adoption, and ineffective programs by health plans and pharmacy benefit managers (PBMs) have also played a role.

“There are many factors driving these costs,” he says. “And each patient population, from commercial to Medicare and Medicaid, will feel these rising drug costs differently.”

In Managed Healthcare Executive’s recent Managed Care Pharmacy Survey, specialty pharmacy stakeholders, including providers, consultants, health plans, and pharmacy benefit managers (PBMs), were asked to offer their predictions about what will transpire at the drug manufacturer level as it relates to drug pricing over the next three years.

More than one-third of respondents (37.58%) said they believed they would see a short period of decrease in annual inflation rates, followed by a return to higher rates. That response was followed by the belief that inflation rates on existing products will continue to grow as they have for the past five to ten years (29.7%) and that we will see a prolonged decrease in annual inflation rates due to the increased scrutiny (18.79%). Only 13.94% thought that a substantially greater number of drug manufacturers will decrease their current list prices.

Naik says that the increased focus on drug pricing is valuable as it helps to bring more pricing transparency to patients—giving them the opportunity to make informed decisions on optimal treatment strategies with their physicians.

He argues it’s really about putting out holistic information about the benefits of the drug treatment and pricing in relation to insurance coverage.

“Commercial drug plan spending has increased by 1.5% in 2018 compared to 3.8% in 2017,” he says. “In 2019, Frost & Sullivan expects lower pricing on drug categories related to pain, high cholesterol, and neurology due to the availability of generics in those segments. Categories related to diabetes, oncology, and HIV, however, will experience inflation due to the launch of new specialty products.”

Despite those projections, Naik says it is important to understand that the current debate about drug pricing is not as simple as just decreasing list prices. He argues it’s really about putting out holistic information about the benefits of the drug treatment and pricing in relation to insurance coverage.

“We have a need to generate simple yet meaningful data,” he says. “Healthcare executives should look at adopting new artificial intelligence or machine learning technologies that can assist standardizing and comparing treatment options with the help of calculator tools to estimate the total out-of-pocket costs for each patient by applying plan specific information.”

By Kayt Sukel
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Life-Altering Gene Therapy Pipeline Poses Challenges

What to expect for these high-dollar drugs.

By Frieda Wiley, PharmD, RPh

The deluge of gene therapy drugs that have entered the market in 2019 foreshadows what industry experts believe will be a continuous push toward personalized medicine. With a variety of new, highly specialized drugs in the pipeline, insiders say the healthcare industry can expect to see shifting treatment models along with dynamic payer challenges for these high-dollar drugs.

“There’s going to be a new paradigm in medicine from a cost and patient perspective,” observes Tami John, MD, an instructor in the department of pediatrics section of hematology/oncology, Baylor College of Medicine in Houston. “From a physician standpoint, we’re advocating for negotiations from the federal, state, and hospital levels because these drugs are going to be life-changing.”

As it stands, managed care organizations are already feeling the fallout of containing the cost of gene therapies currently on the market, with some treatment costs exceeding $1 million. The most expensive drug ever approved, Novartis’ Zolgensma (onasemnogene abeparvovec-xioi), indicated for the rare spinal disorder spinal muscular atrophy, carries a staggering $2.3 million price tag. Although a one-time treatment, the advent of more gene therapies for rare conditions, blood disorders, and cancers brings the question of cost to the forefront.

In reaction to soaring costs, many payers and employers alike have begun implementing stop-loss provisions in their insurance policies to cap spending. Stop-loss policies fall into two general categories, individual and aggregate. Despite being a method to protect payers and corporations from shelling out hundreds of thousands of dollars for tailored treatment, individual policies leave patients on the hook for sizeable out-of-pocket contributions, with deductibles ranging from $40,000 on the low end to as much as $500,000, according to Dominic Galante, chief medical officer of Precision for Value in Buffalo, New York. Meanwhile, aggregate coverage protects against higher than anticipated claim activity for the plan as a whole.

Pipeline Promise

There are numerous gene therapies in the pipeline, and similarly, hundreds of clinical trials are underway. Some trials target rare conditions, including sex-linked conditions such as X-linked granulomatous disease and immunodeficiency disorders, according to clinicaltrials.gov; however, hematologic and oncologic therapies appear to dominate the list, as do therapies entering the pipeline over the next 12 to 18 months.

“I expect gene therapy—within the process of chimeric antigen receptor T-cell (CAR T) therapy—to become an option for more cancers besides relapsed and refractory B-cell lymphoma along with more CAR T-cell treatments for Non-Hodgkin lymphoma and multiple myeloma,” says Vincent Vidaurri, PharmD, BCOP, a clinical oncology pharmacist at the University of Colorado Health in Fort Collins. “However, the greatest impact would be for the treatments of cancer with very poor prognoses such as pancreatic, triple negative breast, and glioblastomas.”

According to new research from Prime Therapeutics, the pipeline includes specialty therapies, such as a calcitonin gene-related peptide (cGRP) drug, an alternative for migraine sufferers on Botox therapy, along with treatments for cystic fibrosis and autoimmune digestive disorders.

On the oncological front, Vidaurri anticipates that healthcare providers will bring the combining of gene therapies with immune checkpoint inhibitors seen in clinical trials to the clinic. He cites combining viral therapy such as talimogene laherparepvec (Imlygic), a genetically engineered product, with a checkpoint blocker such as nivolumab, ipilimumab, or pembrolizumab as examples.

Despite these exciting developments, John cautions that until the payment process is refined, providers should focus on finding local hubs with scientific institutions that have the resources to navigate through payment translation. She advises readers to consider institutions that have access as well as the ability to translate in large volumes to refine techniques as well as forge relationships with the payers.
Beyond Opioids

Pain Management Solutions for the Future

By Nicholas Hamm, Managing Editor

As the opioid crisis rages on, the healthcare industry is looking for alternatives to pain management. The crisis has spurred people from all over the industry, from pharmacists to physicians to healthcare technology companies to pharmaceutical manufacturers, to reconsider their approach.

This type of approach is undoubtedly necessary: Deaths related to opioid doses still kill about 150 Americans every day, according to the National Institutes of Health. One recent study found that Americans are prescribed opioids far more often for surgery than in other similar countries—in Sweden, 11% of patients received opioids after surgery, compared to over 70% in the United States. This is a problem, because around 21 to 29% of patients prescribed opioids develop an addition.

The good news, however, is that opioid prescription rates are declining. According to the CDC, opioid prescribing rates have been falling in recent years, from a high of 81.3 prescriptions per 100 persons in 2012 to 58.7 prescriptions in 2017. Lowering prescribing rates, however, only solves one part of the equation. Patients still need a way to cope with pain, leading many to consider alternate solutions. From acupuncture to novel electrotherapies, here are some of ways healthcare is rethinking pain management.

**Acupuncture**

One of the innovative tools used to move patients away from opioids isn’t so new or innovative at all.

Acupuncture is old—very old. Archaeologists have found evidence of sharpened bones and rocks that they believe were used for acupuncture as long as 8,000 years ago. Now commonly associate with traditional Chinese Medicine, the practice was and has been somewhat on the fringes in Western medicine (and for a significant length of time in China, it was outlawed in 1929 and reinstated in 1949).

In the 1990s, however, acupuncture began to receive more attention. In a 1997 Journal of the American Medical Association article, the National Institutes of Health (NIH) gave "cautious approval of some applications of acupuncture." After looking at the research, NIH concluded that there is evidence the practice helps with post-operative nausea and vomiting, as well as those same symptoms caused by chemotherapy and post-operative dental pain.

Currently, the NIH website says of acupuncture: "Although millions of Americans use acupuncture each year, often for chronic pain, there has been considerable controversy surrounding its value as a therapy and whether it is anything more than placebo. Research exploring a number of possible mechanisms for acupuncture’s pain-relieving effects is ongoing."

But with the opioid crisis comes a need for alternative, non-addictive approaches to pain management, and many believe acupuncture could be a viable solution.

Perhaps the greatest indication that acupuncture has hit the mainstream is a 3-year program sponsored by the Defense and Veterans Center for Integrative Pain Management (DVCIPM), part of the Department of Defense focusing on pain relief. The program trained over 2,800 clinicians—including a number of pharmacists—in what’s known as battlefield acupuncture (BFA).

BFA was developed by Air Force physician Richard Niemtzow in 2001 as a method to relieve chronic pain. It was first tested on U.S. soldiers in Iraq and Afghanistan for efficacy—Niemtzow called it BFA because unlike other therapies, it is easy to administer and transport. It works by putting small studs in specific points on the ear in the hope that they will relieve pain. While Niemtzow says, according to a recent Military Times article, that he has seen significant results and that he hopes the treatment could provide alternatives to opioids, he adds that this is just one new tool in the arsenal against pain—he often encourages patients to seek other complementary treatments or oral therapies.

Another sign that acupuncture may become more common comes from CMS, which is currently considering covering acupuncture to treat chronic lower back pain under Medicare.

Shital Parikh Mars, CEO, Progressive Care, a pharmacy and technology company based in Hallandale Beach, FL, says "Medicare beginning to open these doors for patients is a great thing, because physical therapies like chiropractic care, acupuncture, and massage are
less toxic to the body when performed by fully qualified professionals. These therapies can help manage pain before the patient seeks opioid treatment or even does bodily damage from long term frequent NSAID use."

Mars’ experience with acupuncture is personal: she suffered from stress-induced neck and back pain, of which acupuncture “worked better for me than alternatives that I have tried.” She says healthcare in the future will likely experiment with these alternative therapies, and it would “behoove most standard medicine practitioners to open up their service offerings and begin presenting these alternative treatments to their patients. But first and foremost, education is necessary so that both doctors and patients understand the diagnosis, what options are available, what success and results look like, treatment durations, risks, costs, etc.”

New Technologies
Looking to the past isn’t the only available option for those looking for opioid alternatives.

One of the new trends for pain relief seekers is the use of electrical therapy to stimulate nerves. A recently approved example is Nerivio from Theranica. Nerivio is an app-connected device worn as an armband that utilizes Remote Electrical Neuromodulation (REN) to treat migraines. The device is worn for 45 minutes on the upper arm where it stimulates mainly small skin nerves.

The results speak for themselves: in a study published in the Journal of Headache and Medicine that compared REN with traditional, patient-preferred therapies, researchers found that 2/3 (66.7%) of patients undergoing REN therapy experienced relief compared to 52.5% of those who underwent traditional therapies. Based on these findings, the researchers concluded the REN is an effective alternative and may even be worth looking at as a first-line treatment.

Other available technologies relying on electrical stimulation include Cefaly, sTMS mini, and gammaCore.

This is good news for patients looking to get away from opioids or other medications. While migraine-specific drugs—as well as more common approaches like OTC NSAIDS (which are themselves responsible for a large number of side effects)—are available, opioids continue to be prescribed for migraine patients at high rates, according to the American Headache Society.

Perhaps it’s unsurprising then, that the market for this kind of technology is expected to boom in coming years. While issues of reimbursement and access still exist, one report from Global Market Insights found that the worldwide market for neurostimulation devices is set to hit $16 billion by 2024, growing at a CAGR of 15%. While part of that growth is for non-pain related treatments for neurological conditions (e.g., Parkinson’s disease, epilepsy, dementias), much of that growth will be driven by patients in pain resulting from failed back surgery, as well as for chronic pain sufferers.

### TABLE 1

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<tr>
<td>2017</td>
<td>191,218,272</td>
<td>58.7</td>
</tr>
</tbody>
</table>

Source: CDC
A recent study from the University of Nottingham found that more than half of the patients taking statins did not optimally lower their cholesterol, placing those patients at an increased risk of a heart attack or stroke.

For the 56 million U.S. adults, 40 or older, who have high cholesterol, statins can be a lifesaver. The American Heart Association has long recommended statin therapy as a way to lower LDL cholesterol and reduce the risk of a heart attack or stroke in patients who already have heart disease or who exhibit risk factors, such as being obese or smoking, having high cholesterol, diabetes, or high blood pressure.

"Several dozen trials in the past 30 years have demonstrated efficacy and safety of these medications in cardiovascular risk reduction," says Dr. Rhonderson Cardoso, a cardiology fellow at Johns Hopkins Medicine, Division of Cardiology. "While the study did not detail the reasons for patients having a suboptimal response, one reason may be that the patients were not taking the right statin. According to Cardoso, those study participants with a less than optimal response were prescribed lower-intensity statin therapy and the study used the standard of a 40% reduction in LDL-C that only applies to patients started on high-intensity statin therapy. When it comes to primary prevention, most patients are started on a moderate-intensity statin, which only decreases LDL-C by 30-50% on average.

"Therefore, over a 40% reduction in LDL-C is not anticipated across the board in primary prevention patients," says Cardoso.

The study mentioned, but did not detail, the incidence of noncompliance. While some patients’ statin regimen may need adjusting to work more efficiently, the most common reason that regimens don’t work is that patients don’t take the statin.

"It is nearly impossible for patients not to reduce cholesterol if they take a statin as prescribed," says Joseph Saseen, PharmD, professor and vice chair, department of clinical pharmacy, University of Colorado Anschutz Medical Campus. "Some may not see optimal reduction, but if cholesterol is not lowered, it is 99.99% because of nonadherence."

In some cases, patients don’t take statins as prescribed because they don’t fully understand the purpose of their medication or have misconceptions that lead them to be skeptical of the benefits versus risks.

"Pharmacists are in an excellent position to help out with this, as we are the last step between picking up the prescription and taking the medication regularly to decrease the risk of medical harm (heart attacks, strokes, etc.)," says Saseen.

There are several reasons patients may not fill or refill a statin prescription. One is the lack of obvious symptoms associated with elevated cholesterol. Patients may have a prescription, but they don’t feel sick.

"It’s not like having a cold, where you feel symptoms and take something to feel better," says Stefanie Ferreri, PharmD and APhA spokesperson. "You take a statin because a physician tells you to, but you don’t feel sick. That’s why patient education—every time a patient fills a prescription—is an important part of ensuring that patients will continue to take their prescriptions. The study did not touch on patient education."

Intervention has proven to be successful at helping patients comply with therapy. An NIH study found that about 33% of patients will stick to therapy when given a prescription by their doctors, while about 15% to 25% will not adhere despite any intervention. However, there is the middle 50% of patients who may follow a regimen if given support and encouragement.

Some patients may see filling a statin
it’s possible to tweak it. For a start, there

be exercising. “"You probably still

In any case, a pharmacist can help patients work like it’s supposed to or to completely go off it,” says Beckner. “That will obviously result in it not having the desired effect.”

If soreness and pain are mild to moderate and tolerable, it’s usually advisable to continue treatment and see if the symptoms subside.

“I think that in general the side effects do diminish over time,” says Swartz. “People do get used to it. People may start taking statins and decide right away that they can’t do so and want to stop taking it. Medications with fewer side effects are always an option.”

However, the most noted “side effect” of statins, says Saseen, is that statins save lives.

“Some patients, up to 10% based on studies in real world populations, have side effects,” says Saseen. “Instead of just giving up on the statin, work with your pharmacist to find a different statin or a different dosing scheme that works for you and results in no side effects, in the event they happen.”

Risk factors that decrease statin breakdown rate and increase likelihood of side effects:

1. Medications, including: cyclosporine, gemfibrozil, antifungal azoles, macrolide antibiotics, and protease inhibitors.

2. Mutation in the SLC01B1

3. Age

weakness and pain it causes them to either not take the drug like they are supposed to or to completely go off it,” says Beckner. “That will obviously result in it not having the desired effect.”

If soreness and pain are mild to moderate and tolerable, it’s usually advisable to continue treatment and see if the symptoms subside.

“I think that in general the side effects do diminish over time,” says Swartz. “People do get used to it. People may start taking statins and decide right away that they can’t do so and want to stop taking it. Medications with fewer
Non-Statin Muscle Soreness

“If the pain is persistent, intolerable or severe, then contact your physician,” says Saseen. “They can check three different blood tests to see if there is something ongoing with your muscles (i.e., a serum creatine kinase) or if there is another cause of muscle symptoms (low serum vitamin D or hypothyroidism as indicated by an elevated serum thyroid stimulating hormone).”

True myopathy, with elevated enzymes of muscle injury and rhabdomyolysis, is exceedingly rare, with only a handful of cases for every 10,000 treated patients.

“There is also a mild increase in diabetes although such risk is primarily restricted to patients with significant risk factors for developing diabetes and there is a clear net benefit in terms of risk reduction with statin therapy even in this population,” says Cardoso. “Finally, the data suggesting over-prescription is dwarfed by data suggesting that under-prescription is much more of a problem.”

If a patient can’t take a statin or if statins don’t sufficiently lower cholesterol or cardiovascular disease risk, non-statin therapies such as Ezitimibe or PCSK9 inhibitors may be added to the regimen.

Pharmacogenomic or gene-drug testing is also being used to pinpoint what medication might work best. These tests look for genetic variants to help determine which medication might be an effective treatment and whether you might have side effects to a specific medication.

“Increasingly, pharmacogenomic tests are coming into play,” says Beckner. “A pharmacist can do a genetic test to see which statin drug might not work at all because a patient’s system might not break it down.”

Pharmacists can administer the test and send it to the lab for results, which then come back to the doctor who interprets the results. In a community pharmacy setting, pharmacists can ask patients to bring in their lab values related to cholesterol.

“Pharmacists can then help determine what goal patients should be aiming at,” says Ferrari. “Then, a pharmacist can check to see if they are taking the correct statin and dose.”

“When someone tells me they are not taking medication or they are going to stop taking the medication, I ask them why,” says Swartz. “We can discuss it. So, at least they are not going off medication completely. I am really not in the business of recommending one statin over another. I don’t see that as my role. I like to arm patients with information so they can talk to their healthcare provider.”

Patient education can help prevent cardiovascular events by stressing the importance of compliance and by suggesting adjustments to personalize regimens.

A few statin manufacturers contacted for this story did not respond to questions about the study’s results, as it pertained to this article. Pfizer, which produces Lipitor, chose not to comment as the study covered statins across the board and did not concern a particular statin.

BIGGEST SIDE-EFFECTS

1. Muscle-related issues

Reported rates of 0.3% to 33%. The wide range reflects different populations, as well as different definitions of muscle issues. Statin-induced myopathy is generally defined as muscle pain, weakness, and/or cramps with blood creatine kinase (CK) levels at least 10 times the normal upper limit. CK, while an essential enzyme for muscle function, is a marker for muscle damage when found in elevated levels in the blood.

One rare disorder to note: statins may be environmental triggers for anti-HMG-CoA reductase necrotizing autoimmune myositis which causes severe muscle cell death caused by an autoimmune response against the enzyme that statins target. It likely targets those with underlying genetic susceptibility. Immediate treatment is with immunosuppressants.

2. New-onset diabetes

One study found a 25% increase in new diabetes cases in statin patients compared to others, which increased when more risk factors were present.

3. Increased hemorrhagic stroke incidence

While the risk of ischemic stroke (obstructed blood flow to tissues) is lowered with statins, the risk for a hemorrhagic stroke (a brain aneurysm or blood vessel leak) is associated with lower LDL-C.
In May 2019, the FDA approved tafamidis meglumine (Vyndaqel, FoldRx, a subsidiary of Pfizer). It is one of the first FDA-approved treatments for heart disease (cardiomyopathy) caused by transthyretin-mediated amyloidosis (ATTR-CM) in adults. Transthyretin-mediated amyloidosis is described as a rare, slow progressive condition caused by the buildup of abnormal deposits of proteins in the body’s tissues and organs, debilitating their normal daily function. Tafamidis meglumine was granted Fast Track, Priority Review, and Breakthrough Therapy designations by the FDA. Additionally, this medication received Orphan Drug designation.

Efficacy
The FDA approved tafamidis meglumine primarily based on the results of a double-blind, randomized, 441-participant clinical trial during which participants received either tafamidis meglumine or placebo. Patients aged between 18 to 90 years old with transthyretin amyloid cardiomyopathy (ATTRwt or ATTRm) confirmed by the presence of amyloid deposits on analysis of biopsy specimens obtained from cardiac and noncardiac sites, and in patients without ATTRm, by the presence of transthyretin precursor protein confirmed on immunohistochemical analysis, scintigraphy, or mass spectrometry were eligible. Patients were excluded if any one of the following criteria were met: heart failure that was not due to transthyretin amyloid cardiomyopathy, New York Heart Association (NYHA) class IV heart failure, the presence of light-chain amyloidosis, a history of liver or heart transplantation, an implanted cardiac device, previous treatment with tafamidis, an estimated glomerular filtration rate lower than 25 ml per minute per 1.73 m² of body surface area, or liver transaminase levels exceeding two times the upper limit of the normal range. Patients were given 20 mg tafamidis, 80 mg tafamidis, or placebo administered once a day for 30 months. The primary outcome measure was to assess all-cause mortality, followed by frequency of cardiovascular-related hospitalizations over the course of the 30-month trial. The results showed all-cause mortality was lower with tafamidis than with placebo (78 of 264 [29.5%] vs. 76 of 177 [42.9%]; hazard ratio, 0.70; 95% CI, 0.51 to 0.96). The rate of cardiovascular-related hospitalizations (0.48 vs. 0.70 hospitalizations per year; relative risk ratio, 0.68; 95% CI, 0.56 to 0.81) was lower with tafamidis than with placebo.

Safety
As of publication, there are no known adverse effects associated with tafamidis.

Dosing
In patients with confirmed cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis to reduce death and hospitalization related to heart problems, the recommended dosing for tafamidis meglumine is 80 mg daily by mouth. Doses may not be crushed or cut. If a dose is missed, take the dose as soon as remembered or skip the missed dose and take the next dose at the regularly scheduled time. It is important not to double the dose. Tafamidis meglumine currently has no known drug interactions. Patients should not take tafamidis meglumine if they are pregnant or plan to become pregnant, or if they are breastfeeding or plan to breastfeed. As of right now, the safety and effectiveness of tafamidis meglumine have not been established in pediatric patients. For geriatric patients, no dosage adjustment is required.

References
Like other areas of healthcare, diabetes management in 2019 has been experiencing a combination of new device developments and improvements, technological advancements, new drug approvals, and new partnerships offering a glimpse of distant future possibilities.

Here are five noteworthy products and updates that are making waves in the diabetes management space this year:

**Omnipod DASH + App**

The OmniPod DASH + APP from Insulet is a simple two-part system consisting of a tubeless, wireless, waterproof, and Bluetooth-enabled wireless technology pod that can hold up 22 units of U-100 insulin; and a modern, color touchscreen Personal Diabetes Manager that controls the pod. A small, flexible cannula inserts automatically with the push of a button.

Patients, healthcare providers, and caregivers can choose from a suite of optional mobile apps to help simplify diabetes management.

The FDA recently cleared the OmniPod DASH system as an Alternate Controller Enabled Infusion (ACE) Pump. According to the FDA, the pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, and to receive, execute, and confirm commands from external devices.

**Afinion HbA1C Dx**

This in vitro diagnostic test is the first test that can be used to diagnose and monitor patients with diabetes or pre-diabetes at the point of care in about three minutes.

The Afinion HbA1C Dx is a fully automated coronary affinity assay that determines the percent of glycated hemoglobin in human venous and capillary whole blood.

Blood samples are automatically diluted and mixed with a solution that releases hemoglobin from erythrocytes, creating precipitation. The sample mixture is then transferred to a blue boronic acid conjugate, which binds to the cis-diols of glycated hemoglobin. The mixture is then soaked through a filter membrane that collects precipitated hemoglobin and conjugate-bound and -unbound remains. Excess conjugate is removed with a washing agent.

Boxed warnings for the Afinion HbA1C Dx include the potential development of thyroid C-cell tumors. According to a release, the tumors developed in rodent trials, but the potential for C-cell tumor development in humans with the use of semaglutide is still unknown.

**Oral Semaglutide**

The FDA recently approved oral tablet administrations of Novo Nordisk’s Ozempic (semaglutide) under the new product name Rebylinus.

7 mg and 14 mg tablets are now available for the treatment of patients with type 2 diabetes that, along with diet and exercise, are believed to improve blood glucose levels. Semaglutide was originally approved by the FDA in 2017 the first glucagon-like peptide-1 (GLP-1) analog in a pill for the treatment of patients with type 2 diabetes who are not achieving their A1C goals with current antidiabetic treatments.

Boxed warning for semaglutide include the potential development of thyroid C-cell tumors. According to a release, the tumors developed in rodent trials, but the potential for C-cell tumor development in humans with the use of semaglutide is still unknown.

Semaglutide is contraindicated in patients with a personal or familial history of MTC or in patients with multiple endocrine neoplasia syndrome type 2, according to a boxed warning in the product’s prescribing information.

Other warnings issued with the use of semaglutide include the potential for pancreatitis, diabetic retinopathy complications, hypoglycemia, acute kidney injury, and hypersensitivity reactions.

Adverse reactions reported with the use of semaglutide include nausea, abdominal pain, diarrhea, decreased appetite, vomiting, and constipation.
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13. Publication Title: Drug Topics
14. Issue Date for Circulation Data Below: August 2019
15. Extent and Nature of Circulation

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   b. Total Requested and Paid Print Copies | 87,547 | 85,084 |
   c. Total Requested Copy Distribution (Line 15f) + Requested/Paid Electronic Copies | 122,388 | 122,390 |
   d. Percent Paid and/or Requested Circulation (Both Print & Electronic Copies) | 58.32% | 58.23% |

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Date: 9/30/19
I certify that the statements made by me above are correct and complete.

FreeStyle Libre and Smart Pens
Abbott and Sanofi have recently partnered to combine the former’s FreeStyle Libre technology with the latter’s insulin dosing information for future smart pens, insulin titration apps, and cloud computing software. FreeStyle Libre reads glucose levels through a sensor worn on the back of the upper arm, thereby eliminating the need for finger sticks.

The LibreLink App enables users to capture and view real-time glucose levels, eight-hour glucose history, and glucose level changes in real time on their smartphone.

AgaMatrix + LifeWallet
AgaMatrix—a New Hampshire-based company developing, manufacturing, and marketing solutions for blood glucose monitoring data management on mobile and cloud platforms and LifeWallet—a digital healthcare company—have announced a new partnership to integrate AgaMatrix’s Bluetooth blood glucose monitoring systems with LifeWallet’s apps for health risk assessment and follow up care.

The integration will occur through Apple’s Healthkit, and will also allow clinicians to monitor patients’ daily habits and compliance to a tailored care plan through LifeWallet’s Engage App.

“By incorporating our glucose monitor into LifeWallet’s app ecosystem, it reduces the inefficiencies of traditional manual entry—providing a simplified testing experience for users that is intelligently designed to collect data with minimal disruption,” said John Alberico, President and CEO of AgaMatrix.

LifeWallet is also currently piloting a Sugar Smart for Life Program with West Kendall Baptist Church. Participants in the program undergo health risk assessment to establish prediabetes risk. Those whose levels fell within a pre-diabetic range received wearable devices to capture data such as blood glucose, through AgaMatrix’s Bluetooth-enabled Jaz Wireless 2 Blood Glucose Meter, with the intention of helping them understand the impact that clinical remote monitoring engagement may have on reducing blood glucose levels.."
On July 15, my daughter Gretchen Garofoli appeared before the Senate Subcommittee to discuss financial barriers to adult immunizations. The night before she headed to Washington DC, I said “nothing to worry about GG, but please while you’re there get me an appointment to the FDA. I’ll have them straightened out in a couple of months before I get fired!”

Many of us in healthcare feel that the Food and Drug Administration (FDA) are in the back pockets of the drug companies. It seems that the FDA are always catering to the desires of the pharmaceutical manufacturers. In a previous column in September 2018 (https://www.drugtopics.com/blog/what-fda-needs-do), I implored the FDA to standardize the appearance of all generic drugs. This would show beyond a doubt that the FDA is concerned about patient safety. No one ever contacted me. Hey, I’m just a community pharmacist whose major concern is always the safety of his patients. Heck, old Kreckel doesn’t even have a political action committee!

Back in October 2013, my niece Rachel Fritz was staying at our home when she was doing an optometry rotation in State College. I presented an online lecture on optometry at the college. After I completed my lecture, she asked “Uncle Pete, why didn’t you tell them about the cap colors on ophthalmic products?” Rachel explained that the anticholinergics had red caps, prostanooids had teal caps, anti-inflammatories had grey caps, antibiotics had brown caps, et cetera. In over 30 years of community practice, I never had this explained to me. I’ve yet to meet a pharmacist who ever had this covered in pharmacy school. The American College of Optometry pushed the FDA for this, they even provided the pantone colors to minimize variations on the color green! http://bit.ly/33O6Wq7

Last week, at the doctor’s clinic I work at, once again there was great confusion regarding the asthma/COPD inhalers. I’ve complained about this for years that there is no standardization of asthma inhalers with respect to appearance. We’ve heard horror stories of people using steroid inhalers for emergency, and no one steps up to push standardization.

My niece, now Dr. Fritz, says that optometrists use these color codes to talk with patients. “Use the yellow cap (Timolol) twice daily, and your teal color cap (Xalatan) at bedtime.” She says during post-refractive surgery, it is less complicated when instructing patients when to use the red, gray, and brown cap colors.

I’d like to see the FDA take the initiative to resolve this issue. I’ve heard some of the sales reps say they would have to retool their equipment to change these colors. Fifteen years ago, we were selling generic albuterol inhalers for $8.00 each, and the FDA had the manufacturers change the valves to accommodate CFC-free formulations, to minimize chlorofluorocarbons that were allegedly damaging the ozone layer. Albuterol inhalers all cost over $50 now. Most of the other inhalers for asthma or COPD cost over $300. Certainly, the lives of my asthma and COPD patients deserve as much attention as the ozone layer.

### Table: Kreckel’s Proposed Color Codes

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<td>Green 7481C</td>
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<tr>
<td>Fluticasone, budesonide</td>
<td>Corticosteroids (ICS)</td>
<td>Blue 324C</td>
</tr>
<tr>
<td>Salmeterol, vilanterol, olodaterol</td>
<td>Long Acting Beta Agonists (LABA)</td>
<td>Yellow 107C</td>
</tr>
<tr>
<td>Combination</td>
<td>ICS/LABA</td>
<td>Purple 3520C</td>
</tr>
<tr>
<td>Combination</td>
<td>LAMA/LABA</td>
<td>Brown 2313C</td>
</tr>
<tr>
<td>Combination</td>
<td>LAMA/LABA/ICS</td>
<td>Gray 400C</td>
</tr>
</tbody>
</table>

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