How Pharmacy Will Change in 2019

Four trends that will shape business and the profession

MERGERS AND ACQUISITIONS

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How the 2018-2019 Flu Shots Help Protect the Public

The 2018-2019 flu season has been off to a slow start, but that doesn’t mean patients should skip getting a flu shot or that pharmacists can skimp on recommending them. “Flu activity has been low so far this year, but we expect activity will pick up soon and peak between December and February,” said Alicia Budd, MPH, an epidemiologist in the Influenza Division of the CDC’s National Center for Immunization and Respiratory Diseases.

According to Budd, Influenza A (H1N1) is the predominant flu virus circulating so far this season. “Last season the flu vaccine reduced H1N1 risk by 65%.”

The success of any season’s flu vaccine depends on how well it matches the three or four viruses most likely to strike. As viruses evolve, vaccines are updated to counter new strains.

The roster of approved vaccines for the 2018-2019 season includes inactivated injectable vaccines (IIV), recombinant flu vaccines (RIV), and live attenuated vaccine (LAIV), which was omitted last year. The CDC expresses no preference, as long as vaccines are licensed and age-appropriate.

Trivalent or Quadrivalent?

Although trivalent and quadrivalent vaccines are both available this season, manufacturers estimate that up to three-quarters of the flu vaccines administered this season will be quadrivalent because the vaccine’s extra component protects patients from another strain of influenza.

Trivalent flu vaccines are designed to protect against three virus strains, two A viruses (H1N1 and H3N2) and one B virus, but there’s often more than one B virus circulating during any flu season. Quadrivalent vaccines offer more protection by adding a second strain of B virus.

Although quadrivalent flu vaccines offer broader protection, the CDC does not recommend waiting in the event there’s a shortage. Getting a trivalent flu shot when you can is considered more effective than waiting for a quadrivalent vaccine.

What’s Changed This Season?

Both trivalent and quadrivalent vaccines contain the same H1N1 virus as last season. Updates were made to the H3N2 virus, and the B virus is a different strain from last year.

Components in this year’s trivalent vaccine are:

- **Type A H1N1:** A/Michigan/45/2015 (H1N1)pdm09-like virus, same as last year.
- **Type A H3N2:** A/Singapore INFIMH-16-0019/2016 A(H3N2)-like virus, updated.
- **The B virus this season is different, B/Colorado/06/2017-like (Victoria lineage) virus updated.**

Quadrivalent vaccines feature an additional B virus:

- **B/Phuket/3073/2013-like (B/Yamagata lineage) virus, which is the same as in the 2017-2018 flu vaccine.**

This year’s trivalent vaccines come in a standard dose for ages 18 through 64 and a stronger dose for people over 65 because a higher dose of flu vaccine is more effective in older adults.

A cell-based flu vaccine offers options for patients with egg allergies since this type is grown in mammalian cells rather than in chicken eggs. The virus may contain traces of albumin, so people with history of severe egg allergy should be vaccinated in a doctor’s office, where any allergic reaction can be monitored and treated.

CONTINUED ON BACK
Patients who don’t like needles can get the trivalent flu vaccine via an intradermal shot, which inserts medicine under the skin, or a jet injector, which uses a high-pressure stream of fluid.

**Nasal Spray**
Nasal sprays are also back on the approved vaccine list due to an improvement in formula. A quadrivalent nasal-spray vaccine is now recommended for non-pregnant individuals who are two years through 49 years of age.

There are some important exclusions with the nasal-spray vaccine. Children age two through 17 who take aspirin- or salicylate-containing medications; as well as children age 2 to 4 who have asthma; and anyone with a weakened immune system, should not be administered the nasal vaccine.

Even though flu season is already underway, immunization is still recommended for everyone over six months of age. Flu shots are especially important for young children, adults 65 years of age and older, pregnant women, and people with asthma, diabetes and heart disease.

“So far six flu-related pediatric deaths have been reported this flu season,” Budd said. “Each season most pediatric deaths are in children who aren’t vaccinated.”

### Table: 2018-2019 Vaccine Options and Suitability

<table>
<thead>
<tr>
<th>TRADE NAME [MANUFACTURER]</th>
<th>PRESENTATION</th>
<th>AGE INDICATION</th>
<th>HA, μG/DOSE (EACH VIRUS)</th>
<th>EGG-GROWN VIRUS, CELL CULTURE-GROWN VIRUS, OR RECOMBINANT HA</th>
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<tbody>
<tr>
<td><strong>QUADRIVALENT IIVS (IIV4S)</strong></td>
<td></td>
<td></td>
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<tr>
<td>Afluria Quadrivalent [Seqirus]</td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;3 yrs</td>
<td>15</td>
<td>Egg</td>
</tr>
<tr>
<td></td>
<td>5.0 mL multidose vial</td>
<td>&gt;6 mos (needle/syringe) 18 through 64 yrs (jet injector)</td>
<td>7.5/0.25 mL 15/0.5 mL</td>
<td>Egg</td>
</tr>
<tr>
<td>Fluax Quadrivalent [GlaxoSmithKline]</td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;6 month</td>
<td>15</td>
<td>Egg</td>
</tr>
<tr>
<td>FluLaval Quadrivalent [ID Biomedical Corp. of Quebec]</td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;6 month</td>
<td>15</td>
<td>Egg</td>
</tr>
<tr>
<td></td>
<td>5.0 mL multidose vial</td>
<td>&gt;6 month</td>
<td>15</td>
<td>Egg</td>
</tr>
<tr>
<td>Flucelvax Quadrivalent [Seqirus] (ccIIV4)</td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;4 yrs</td>
<td>15</td>
<td>Cell</td>
</tr>
<tr>
<td></td>
<td>5.0 mL multidose vial</td>
<td>&gt;4 yrs</td>
<td>15</td>
<td>Cell</td>
</tr>
<tr>
<td>Fluzone Quadrivalent [Sanofi Pasteur]</td>
<td>0.25 mL prefilled syringe</td>
<td>6 through 35 months</td>
<td>7.5/0.25 mL</td>
<td>Egg</td>
</tr>
<tr>
<td></td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;3 yrs</td>
<td>15/0.5 mL</td>
<td>Egg</td>
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<tr>
<td><strong>TRIVALENT IIV (IIV3S)</strong></td>
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</tr>
<tr>
<td>Afluria [Seqirus]</td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;3 yrs</td>
<td>15</td>
<td>Egg</td>
</tr>
<tr>
<td></td>
<td>5.0 mL multidose vial</td>
<td>&gt;6 mos (needle/syringe) 18 through 64 yrs (jet injector)</td>
<td>7.5/0.25 mL 15/0.5 mL</td>
<td>Egg</td>
</tr>
<tr>
<td>Fluad [Seqirus] (allIIV3)</td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;65 yrs</td>
<td>15</td>
<td>Egg (adjuvanted with MF59)</td>
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<tr>
<td>Fluzone High-Dose [Sanofi Pasteur] (HD-IIV3)</td>
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<td>&gt;65 yrs</td>
<td>60</td>
<td>Egg</td>
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<tr>
<td><strong>QUADRIVALENT RIV (RIV4)</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flublok Quadrivalent [Sanofi Pasteur]</td>
<td>0.5 mL prefilled syringe</td>
<td>&gt;18 yrs</td>
<td>45</td>
<td>Recombinant</td>
</tr>
</tbody>
</table>

Source: CDC
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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.

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As the country grapples with the opioid abuse epidemic, communities are working together to have conversations, engage with partners and develop solutions to prevent the improper use of these medicines. Prescription opioid abuse and misuse is a serious and sensitive topic because misuse of these medicines often starts in the home. Patients and their caregivers need to be able to turn to a trusted and accessible healthcare provider. Often, that person is their local pharmacist.

Pharmacists play a crucial role in educating patients about the potential risks and side effects of the medicine every time they pick up or refill a prescription. By having these important conversations, pharmacists can ensure that their patients who are prescribed an opioid understand the serious risks associated with these medicines, which include dependence, addiction, or overdose, especially with prolonged use.

Pharmacists also have the opportunity to remind patients of the steps they can take to ensure opioids do not end up in the wrong hands. These include knowing how to safely use and securely store opioid pain medications when they are prescribed and how to promptly dispose of any unused or expired pills.

Right now, there is a persistent and growing gap in education and awareness on the proactive steps that can be taken to mitigate the risk of misuse before it occurs. A poll conducted by Morning Consult in 2018 underscored the lack of awareness among consumers about prescription opioid safety and highlighted the need for more focused education around safe use, storage, and disposal of these pain medications.

For instance, 36% of respondents said they did not know they needed to dispose of leftover prescription opioids, and nearly 30% said they did not know how to do so safely. However, nearly 70% said that, with detailed instructions, they would be more likely to securely store and properly dispose of prescription opioids.

Allied Against Opioid Abuse (AAOA), a national initiative to help prevent prescription opioid abuse and misuse through education, has joined efforts to raise awareness about the rights, risks, and responsibilities associated with prescription opioids. AAOA has convened national and local partners from across the pharmaceutical supply chain, public health, and healthcare to work together to educate patients and their families about opioid safety prevention methods, including the safe use, storage, and disposal of these pain medicines.

Our organizations worked with AAOA to engage and mobilize the pharmacy community in patient education efforts around prescription opioid safety. Together with state pharmacy associations in Connecticut, Florida, Minnesota, Ohio, Pennsylvania, and Tennessee, we developed a pharmacy toolkit to equip the pharmacy community with resources to help prevent and reduce instances of prescription opioid abuse and misuse in the communities that they serve.

The AAOA Pharmacy Toolkit provides educational materials to help pharmacists engage in conversations with their patients and healthcare provider colleagues about prescription opioids and how to prevent abuse of these pain medications. Key components of this educational effort encourage pharmacists to talk to their patients about the potential side effects and risks associated with opioid medications; safe use and taking the medication only as prescribed; alternative pain treatments and other ways to manage pain; and proper storage and the prompt disposal of unused pills.

We believe that increasing public education and awareness of prescription opioid safety is an important step to reversing the trend of misuse and abuse in communities nationwide.

By arming pharmacists and pharmacy staff with resources and materials that focus on the rights, risks, and responsibilities associated with prescription medicines, they will be able to provide pain-management guidance to patients with legitimate needs for opioids and help to minimize instances of misuse of these medicines in the home.
Despite last year’s influenza season being one of the worst in a decade, many Americans don’t plan to get the flu shot, a new survey says.

By mid-November, 43% of the more than 1,000 consumers surveyed said they had gotten a flu shot, while 41% said they had not been vaccinated and do not intend to be, according to the National Opinion Research Center (NORC) at the University of Chicago survey.

When asked why they did not intend to be vaccinated, 36% of consumers said they were concerned about side effects from the vaccine. Thirty-one percent say they don’t believe the vaccine works well. In addition, 31% cited concerns about getting sick from the vaccine.

Thirty percent said a major reason they do not get vaccinated is because they never get the flu. “Unfortunately, many people are still not getting flu shots due to broader misconceptions about the value of receiving a flu shot and concerns about the safety and efficacy of the vaccines,” says Caitlin Oppenheimer, senior vice president of Public Health Research for NORC at the University of Chicago, in a statement.

People rarely cited barriers to access—such as the vaccine costing too much (6%) or not having time to get it (5%)—as reasons they would not be vaccinated.

People age 60 and older reported the highest vaccination rate at 62%. However, 24% of people over 60 still do not plan to get vaccinated this season.

Adults under age 45 are the least likely to report being vaccinated, NORC finds, and around 50% of this group said they do not plan to receive a flu vaccine.

The CDC estimates that flu vaccination coverage among adults was 37% for the 2017-2018 season and 43% for the 2016-2017 season.

Major reasons people do not plan to get a flu vaccine

- 36% Concerned about side effects from the vaccine
- 31% Believes that flu vaccines do not work very well
- 31% Concerned about getting the flu from the vaccine
- 30% Never get the flu
- 27% Unlikely to get sick from the flu

Other responses included: Some other reason: 13%; Vaccine costs too much: 6%; Have a health condition that prevents vaccination: 5%; Don’t have time to get a vaccination: 5%; Allergic to the vaccine: 5%.

Source: NORC at the University of Chicago, AmeriSpeak® Spotlight on Health
Nurses, doctors, and pharmacists are considered the most honest and ethical professions, according to the annual Gallup Poll rating of professions. Nurses top the list for the 17th consecutive year with 84% of respondents saying the honesty and ethical standards of nurses are high/very high; 67% say the same about medical doctors, and 66% say the honesty and ethics of pharmacists are high or very high.

Nurses have reigned as the most honest and ethical since 2001, when firefighters took the top spot following their response to the 9/11 attacks. Nurses ranked second that year, followed by the U.S. military, police, pharmacists, and medical doctors.

Pharmacists regularly rank as the second most honest and ethical profession. Since 2002, pharmacists ceded the second spot to medical doctors just three times, in 2003, 2017, and 2018.

<table>
<thead>
<tr>
<th>Year</th>
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<th>Pharmacists</th>
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<td>79</td>
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<tr>
<td>2018</td>
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<td>67</td>
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Kroger’s Prescription Discount Program to Boost Store Traffic

Kroger Co. is expected to increase traffic to its pharmacies with the recent launch of its discounted prescription loyalty program.

Kroger’s new Rx Savings Club, developed in partnership with GoodRx, provides customers with discounts on commonly-prescribed generic medications for heart health, diabetes, asthma, mental health issues, women’s health, gastrointestinal health, and other conditions.

The program provides up to an 85% savings on thousands of prescriptions, according to the Cincinnati-based operator of more than 2,700 grocery stores and more than 2,200 pharmacies.

For example, atorvastatin (Lipitor) is $6 for a 30-day supply and $12 for a 90-day supply for members of the Rx Savings Club. Free medications include amiodipine for high blood pressure, metformin IR for diabetes, sertraline for mental health, and montelukast for asthma.

Members of the Rx Savings Club pay an annual fee of $36 for individuals and $72 for families (up to six people can be covered with one family membership). The program offers three tiers of low-cost medications:

- **Free, 30-day and 90-day prescription;**
- **$3, 30-day and $6, 90-day prescriptions;**
- **$6, 30-day and $12, 90-day prescriptions.**

"Kroger reaches millions of people a day through its stores, so pharmacy programs are an important way to drive traffic into their stores. The pharmacy business is so competitive that each retailer needs to have its own bonus card or approach to build loyalty among customers," Ashraf Shehata, advisory principal at KPMG and a member of the firm’s Global Healthcare Center of Excellence, tells Drug Topics.

Because the pharmacy business is so aggressive, it is difficult to say how much Kroger’s prescription savings program will drive growth, according to Shehata. However, having a tier of free prescription drugs that includes high blood pressure, antidepressant, asthma and diabetes treatments—will attract the attention of patients utilizing these treatments, “a fairly large segment of the population,” Shehata says.

Compared to many other retailers, Kroger is sophisticated in the use of its loyalty cards and mobile apps, “which generate data to help improve the customer experience,” Shehata says.

Kroger’s approach can help people who do not have a pharmacy benefit manager acting on their behalf, Shehata says. “Also, Kroger’s club can help it keep more of its revenue versus dealing with a pharmacy benefit manager that only pays a small dispensing fee to retail pharmacies.”

“Our mission is to help lower the cost of prescriptions in America, and we are very pleased to have worked with Kroger to develop such a significant Rx savings program,” says Jim Sheninger, pharmacy strategy officer for GoodRx, in a statement. “The popularity of the medications included in these discounts, coupled with the extra low-cost pricing tiers, should result in meaningful savings for patients and families—savings that are absolutely critical in this high-priced healthcare landscape.”
Diabetics Cut Insulin to Save Money

One-fourth of patients with type 1 or type 2 diabetes use less insulin than prescribed because of high out-of-pocket costs of the medication, a new study says.

In the study, published in the Dec. 3 issue of JAMA Internal Medicine, researchers also found that one-third of patients experiencing cost issues do not discuss the problem with their physicians.

“Of patients with HF, influenza vaccination was associated with a reduced risk of both all-cause and cardiovascular death after extensive adjustment for confounders,” the researchers write.

Christine Blank is a contributing editor.

Influenza Vaccine Cuts Heart Deaths

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Long-Acting ‘Smart’ Drugs May Be the Future

A research team is experimenting with long-acting “smart” drug formulations that remain dormant in patients until needed.

Adah Almutairi, PhD, associate professor the Skaggs School of Pharmacy and Pharmaceutical Sciences and director of the Center for Excellence in Nanomedicine at UC San Diego, and his team are experimenting with nanoscale polymer shells that can deliver drugs and diagnostic technology “in ways that are smart enough to respond to disease,” says Almutairi, the keynote speaker at ASHP’s Mid-year Clinical Meeting in December.

ASHP provided a summary of the session on its website.

While it is very challenging to produce polymer shells that can provide a stable system sensitive to the patient’s internal chemistry, “we have been able to achieve this,” Almutairi says.

Almutairi and her team tested the technology for the delivery of antivascular endothelial growth factor therapy in the eye to treat age-related macular degeneration. The polymer shells release the drug only in response to the presence of reactive oxygen species in the eye, leaving much of the initial dose available for later release in response to active signals of disease, she says.

The polymer-shell injection procedure is in stark contrast to the current treatment, which requires patients to undergo intraocular injections several times a year to deliver sufficient medication to the eye to limit the progression of disease.

The nanopolymer technology has also allowed the researchers to diagnose inflammation, indicating the presence of cancer, edema, gout, and rupture-prone arterial plaque in animal models. Almutairi said the team “has confirmed in multiple scenarios that the polymer shells activate only when needed and don’t prematurely release their medication or diagnostic cargo,” ASHP says.
The beginning of a new year usually means that some new government rules and regulations will become effective. For pharmacists, some laws were implemented on January 1, and others are in the works. Here’s a look at five new policies to watch this year.

Changes to Medicare plans for contract year 2019.
These are CMS’ new strategies to help Medicare Part D plans prevent and combat prescription opioid overuse through improved concurrent drug use review and became effective January 1. “There are changes to when a prescription can be filled, including several formulary-level opioid safety changes and modifications related to the point of sale,” says Ronna Hauser, PharmD, vice president of pharmacy policy and regulatory affairs at the NCPA. Medicare Advantage and Part D plans must follow this annual set of proposed rules, guidelines, and clarifications in order to participate in Medicare for the upcoming contract year.

One change, for example, is a care coordination safety edit. Under this edit, if a person’s cumulative morphine milligram equivalent (MME) per day across all of that person’s opioid prescriptions reaches or exceeds 90 MME, “sponsors should instruct the pharmacist to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that indicates the prescriber has been consulted,” according to CMS. “Combating opioid abuse has been at the forefront of the Trump Administration’s healthcare agenda and the Medicare Part D space is a federal program where many of the administration’s policy changes can make a difference,” Hauser tells Drug Topics. “CMS states that its formulary-level modifications seek to combat opioid abuse without impacting access to medically-necessary drugs and hindering a patient’s relationship with their healthcare team.”

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act).
This act encompasses a wide range of issues, including access to treatment for substance use disorder and additional policies that are intended to balance patients’ pain management needs with prevention efforts. “The new law aims to combat the opioid crisis, advance treatment and recovery efforts, improve prevention, protect communities, and guard against deadly illicit synthetic drugs (such as fentanyl),” says Jenna Ventresca, JD, director of health policy at APhA. “Pharmacists should be aware of ongoing federal efforts to address the opioid epidemic as these efforts will directly impact the care pharmacists provide to patients and communities.”

One of the many provisions of the act will require electronic prescribing for Medicare Advantage and Part D schedule II through V controlled substance prescriptions as a way to help deter prescription fraud and diversion. “This would not necessarily limit pharmacists’ ability to dispense prescriptions that are not electronically prescribed or a plans’ ability to cover otherwise valid prescriptions,” she says. “Another facet of the law requires HHS to establish a standard and a secure electronic prior authorization system for covered Part D drugs to streamline care. Prescription drug plan sponsors and Medicare Advantage organizations are required to provide for electronic prior authorization requests from prescribers and subsequent responses by January 2021.”

Since President Trump signed the act into law on October 24, regulatory activity is forthcoming which will provide further details and compliance requirements. “Given the broad scope of the law, it will be important for pharmacists to monitor communications from their professional associations and regulatory entities at the state and federal levels,” Ventresca says.

CMS Hospital Outpatient Prospective Payment Proposed Rule CY 2019 (OPPS).
This proposed rule further expands cuts to the 340B Drug Pricing program made in 2018 and institutes a site-neu

CONTINUED ON PAGE 10
trality payment policy for hospital outpatient departments by cutting reimbursement by 40% for the most commonly reimbursed G-codes in order to match payment under the Physician Fee Schedule, says Jillanne Schulte Wall, JD, director of federal regulatory affairs at the ASHP. The proposed rule also includes a request for information related to a potential Competitive Acquisition Program for Part B drugs and biologics, which would run through the Center for Medicare and Medicaid Innovation.

“The change to the federal 340B program reflects CMS’ continued insistence that the 340B program contributes to high drug prices, while the site-neutrality provision reflects CMS’ efforts to reduce Medicare expenditures,” Schulte Wall says.

Pharmacists should be aware that 2017’s cuts to reimbursement for drugs purchased under the 340B program for use in hospitals are being extended to hospital outpatient departments. Therefore, drugs purchased for the 340B program for use in hospital outpatient departments will now be reimbursed at the average sales price (ASP) minus 22.5%, rather than ASP plus 6%, she says. Final OPPS rules generally take effect on January 1.

Know the Lowest Price Act.

This act was signed into law on October 10 and will become effective either on or after January 1, 2020. The act blocks Medicare Advantage plan providers or providers of a Medicare Part D prescription drug plan from using gag clauses that prohibit pharmacists from alerting Medicare customers of differences between their insurance copay and what the patient would pay without using health insurance coverage, says Ken Majkowski, PharmD, chief pharmacy officer at FamilyWize, which aims to help consumers save money on prescription drugs.

The act was implemented to increase price transparency for consumers covered under Medicare or Medicare Advantage. “Many consumers don’t know to ask if a lower prescription price is available,” Majkowski says. “When a pharmacist knows that a patient is overpaying but can’t share this information, the patient loses a chance to save and pharmacists feel like they aren’t performing to the best of their abilities. Consumers aren’t given the opportunity to make educated choices surrounding healthcare costs.”

Pharmacists can help patients find better pricing by advising that there are options available to them, Majkowski says. Pharmacists may also want to remind patients that if they don’t use their Medicare benefit, they may not be able to apply that purchase to their deductible, if one exists.

Proposed regulations on drug price disclosures in advertisements.

This is the latest proposal in a series of newly proposed congressional bills and FDA regulations that require pharmaceutical companies to disclose their prices in drug advertising, says Edward J. Buthusiem, managing director, Berkeley Research Group, a global consulting firm.

“The new regulation would require pharmaceutical manufacturers to include the wholesale acquisition cost (WAC) of a drug or biologic for a typical month of therapy in televised direct-to-consumer advertisements,” says Jeremy Schafer, PharmD, MBA, senior vice president of director-payer access solutions at Precision for Value, a pharmaceutical consulting firm. “The regulation would impact any drugs or biologics eligible for payment under Medicare or Medicaid—essentially nearly all pharmaceuticals and biologics—with the exception of those with a WAC below $35 per month.”

Schafer says, “HHS Secretary Alex Azar has stated that the intended goal of the new regulation is to reduce the price to consumers of prescription drugs and biologics,” Schafer says. “Increasing price transparency by educating consumers on the cost of drugs so they can make informed decisions is part of the justification for this rule.”

Ahead of this regulation, Buthusiem says pharmacists should be prepared to articulate answers to pricing questions and fill in gaps that advertisements miss. “In a typical in-person interaction, a pharmacist will be the first point of contact and needs to have a deep understanding of the various details, regulations, and plans to provide accurate information to patients,” he says.

Along these lines, Schafer says pharmacists should be aware that patients may ask them about the cost of a drug they saw on TV and what, if any, portion of that the patient may be responsible for. Pharmacists may also be asked if there are less costly alternatives, so pharmacists should be aware of alternatives, whether the therapy and its alternatives may be appropriate, and what the cost may be.

The comment period ended in December, so the rule, as written or modified, could go into effect at any time this year.

Karen Appold is a medical writer in Lehigh Valley, PA.
Woodrow Wilson was president, the First World War was just ending, the Spanish flu pandemic had just started, and Nichols Pharmacy opened in Portland, OR. The pharmacy is still there, after 100 years in one location in the Hollywood district of the city, with two names, three sets of owners, and one still-functioning soda fountain.

Known as Paulsen’s Pharmacy since 1923 when Charles Paulsen, RPh, bought it from the original owner, Frank Nichols, the manner in which it has changed hands illustrates the ways that ownership of a pharmacy may depend on making the right connections. It also illustrates how a modern pharmacy can change some of its main streams of revenue.

Former owner, Gary Balo, RPh, went to work at Paulsen’s right out of pharmacy school in 1970. “I worked there 45 years. I was a partner and owner for 38 of those years,” he tells Drug Topics. He bought the pharmacy with his partner, Jim Mead, RPh, from Charles Paulsen. Mead retired in 1987, according to the store’s website.

Early in Balo’s ownership of the pharmacy, the owners of the building announced that they wanted to tear it down to make way for a McDonald’s. Other tenants in the building moved out, but Balo and the pharmacy stood firm and got the support of the neighborhood with a publicity campaign that saved the building.

Balo says he usually worked at Paulsen’s six days a week, with his wife Karen working alongside him for 35 of those years. “We wanted to start a new chapter in life,” he says. “I wanted a change of pace and to do traveling and volunteer work.”

When Balo decided to retire, he held on for a few years because a former employee had expressed an interest in buying the pharmacy once she had more experience. But it never panned out, and Balo started looking around for someone else to buy it.

A conversation with Gary Basrai, PharmD, that started at a pharmacy convention in August 2015 led to Basrai and his family making an offer for Paulsen’s, Jasmine Basrai tells Drug Topics. “The deal was consummated in April 2016,” Balo says.

The Basrais own several independent pharmacies in Northern California, including Haller’s in Fremont, CA, and Alisal in Salinas, CA, with Jasmine Basrai as manager of operations for all of them.

The main change that the new ownership has brought to Paulsen’s is a new revenue stream. Paulsen’s now has a specialization in hospice pharmacy, Jasmine Basrai says. “Half of our business is hospice pharmacy,” says Huy Nguyen, PharmD, the pharmacist in charge at Paulsen’s.

Nguyen joined the pharmacy after the Basrais purchased it and says that the store’s long history is important to its customers. “When you come into Paulson’s, we know who you are,” he tells Drug Topics. “We know you. Customers have been coming here for 30 or 40 years.”

Although Balo retired so that he could take life easier, the move away from being a community pharmacist for so long was stressful, he says. “When we retired it was a tough three- or four-month transition.” He had third- and fourth-generation customers. We knew their lives. It gets to you. It’s very emotional to sever that.”

Any business that has been in one place for a century will have a lot of mementos and items on hand. Balo and his wife took some souvenirs home, and donated a lot of to the Oregon State University College of Pharmacy. There are still many interesting items on hand, says Nguyen. “We have bottles from 1913 and the 1920s, and handwritten stuff from way back.”

The pharmacy has been renovated in recent years, but the soda fountain still has its original marble countertop. Another thing that hasn’t changed at Paulsen’s is their delivery service. One of the pharmacy’s oldest employees, Ben Schwartzkopf, 81, has been their delivery person for 23 years, making his rounds on weekday afternoons.

Valerie DeBenedette is managing editor of Drug Topics.
THE LIST

By Aine Cryts

10 Pharmacists to Follow on Twitter

There are always pharmacists with something to say that’s worth reading. Some are on Twitter and discuss general pharmacy or areas within the profession. Here are 10 pharmacists worth following.

Jeffrey Bratberg, PharmD
@jebratberg
Clinical professor, University of Rhode Island College of Pharmacy
Jeff Bratberg’s Twitter feed focusses on his specialties of opioid safety, overdose prevention, infectious diseases, public health, and emergency preparedness. In 2012, he codirected an overdose education and naloxone training program for pharmacists in the first statewide Collaborative Pharmacy Practice Agreement for naloxone. Bratberg was the guest editor of the first special issue on opioid safety and naloxone of the Journal of the American Pharmacists Association.

Sally Rafie, PharmD, BCPS, @pharmclinic
Pharmacist specialist at the University of California San Diego Health and founder, Birth Control Pharmacist
Sally Rafie started Birth Control Pharmacist, which provides education, training, resources, and clinical updates to pharmacists who prescribe contraception. She also serves as clinical professor of health sciences at UC San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences and as an advanced practice pharmacist at The Pharmacists Clinic in San Diego.

Buddy Carter, BSPharm
@RepBuddyCarter
Member, U.S. House of Representatives
The only pharmacist currently serving in Congress, Buddy Carter represents Georgia’s first district and is the cochair of the Community Pharmacy Caucus in the U.S. House of Representatives. He also founded Carter’s Pharmacy in Pooler, GA. Carter previously served as mayor of Pooler and in the Georgia General Assembly.

Alyssia D., PharmD @DrDivaRx
PGY1 community-based pharmacy resident at UNC Eshelman School of Pharmacy
A North Carolina-based pharmacy resident and pharmacy educator, Alyssia D. also serves as an adherence advocate. That’s in addition to previous roles as pharmacy peer tutor at Notre Dame of Maryland University and pharmacy intern at CVS Health.

Tyson Cromeens, PharmD @CVSPharmD
Senior advisor and pharmacist recruitment strategist, CVS Health
In his current jobs, Tyson Cromeens manages pharmacy interns and pharmacist relations in addition to hiring in Kentucky, Ohio, and Pennsylvania. A 23-year veteran at CVS Health, Cromeens focuses on enhancing its pharmacists through talent recognition, building strong, high-performing teams, and making sure they’re delivering high quality pharmaceutical care to patients. He’s also responsible for engaging with and delivering candidates for the company’s residency programs.

Bethany Kalich, PharmD @KalichBA
Professor of pharmacy practice at University of Texas Health Science Center in San Antonio, adjunct professor at University of the Incarnate Word Felk School of Pharmacy in San Antonio, and clinical pharmacist, cardiology acute and critical care at University Health System in San Antonio
Before her academic and pharmacist roles, Kalich was a PGY2 critical care pharmacy resident at University Health System in San Antonio. She advocates for the role of healthcare professionals in social media. Reed presented on this topic at the 2018 American College of Clinical Pharmacy Global Conference.

Lisa Padgett, PharmD @LPadgettPharmD
Clinical pharmacist and clinical trials investigator, Medication Management LLC, and community pharmacist, Costco Pharmacy
Based in Raleigh, NC, Lisa Padgett tweets about the patient-centered medical home, interprofessional education, geriatrics, primary care, pharmacy education, community pharmacy, and other topics.

Brent Reed, PharmD, BCPS-AQ Cardiology @brentnreed
Professor at University of Maryland School of Pharmacy and clinical pharmacy specialist at University of Maryland Medical Center in Baltimore
In addition to his role as director of the cardiology pharmacy resident program at the University of Maryland, Brent Reed practices in the areas of heart failure and advanced cardiovascular therapies. He maintains an active online presence and advocates for the role of healthcare professionals in social media. Reed presented on this topic at the 2018 American College of Clinical Pharmacy Global Conference.

Mar Creixell, PhD, PharmD @marcreixell
Senior medical science liaison, Janssen Pharmaceutical Companies of Johnson & Johnson and clinical pharmacist at McKay-Dee Hospital in Ogden, UT
In her role at Johnson & Johnson, Mar Creixell provides scientific information and education to healthcare customers and internal business partners and builds external relationships with experts in therapeutic and managed markets/healthcare systems. At McKay-Dee Hospital, she assesses patients for admission into its anticoagulation clinic, reviews patients’ medical histories, and educates patients and their families about the use of anticoagulation treatment.

Aine Cryts is a medical writer, an avid runner, and proud sharer of her dog, Spotty. @acryts.
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How Pharmacy Will Change in 2019

Four trends that will shape business and the profession

By Beth Longware Duff

The pharmacy industry in the United States continued to evolve in 2018, fueled by ongoing and significant changes in healthcare. The shift from volume-based to value-based care and reimbursement, the rising cost of prescription drugs, a rapid spike in the incidence of chronic diseases, and national health spending that is projected to rise 5.3% this year are all driving healthcare organizations to address costs through economies of scale and efficiencies. Drug Topics has identified four sectors that we expect will continue to dominate and change pharmacy in 2019. They are mergers and acquisitions, automation, telepharmacy, and drug prices. We’ve spoken to experts in each area to get their opinions and prognostications as to what lies ahead.

Mergers and Acquisitions

Consolidation in retail pharmacy will continue in 2019, but don’t expect another banner year like 2018. In September, the U.S. Department of Justice approved Cigna’s $52-billion acquisition of Express Scripts. A month later it greenlighted the $69-billion merger of CVS Health and Aetna—the largest health insurance deal in history. The companies completed the merger in November, but they are still working on final approvals from regulators and the courts, which at press time indicated that some antitrust concerns persist.

The New York Times described the CVS-Aetna merger as both capping “a wave of consolidation among giant health care players that could leave American consumers with less control over their medical care and prescription drugs” and marking “the close of an era, during which powerful pharmacy benefit managers brokered drug prices among pharmaceutical companies, insurers and employers.”

The accuracy of those predictions remains to be seen, but NCPA has expressed its own concerns to federal and state regulators about the negative impacts these mega deals are likely to have on competition,
pharmacy patients, payers, and locally owned pharmacies. “When it comes to healthcare, we’re just not convinced that bigger is better,” says CEO B. Douglas Hoey, RPh, MBA.

NCPA’s position is that patients are likely to be channeled into one-size-fits-all solutions that might not be in their best interest and may actually put more distance between them and their healthcare provider. “Community pharmacies can compete on convenience, affordability, and customized care when the playing field is level,” Hoey says. “Our concern is that these megamergers will silo patients, not for the benefit of their health, but for the benefit of the corporations’ bottom lines.”

Reg Blackburn, managing director of The Braff Group, sees this year’s acquisitions from a business perspective as a continuation of the vertical integrations that have reshaped the industry in recent years.

“If you look at who they are competing with, you have other large players like UnitedHealthcare, which is a larger insurer that also owns OptumRx, which is a PBM that also has a large, specialty pharmacy mail-order business,” he notes. “It’s driven by rising healthcare costs and the desire for the payer—be it CMS, Medicaid, or ultimately the company that’s processing their claims through one of the large insurance companies—to try to get control of their costs. There’s an evolving belief, even within CMS, that paying per-line-item versus paying in a more holistic way is where the future is headed.”

There are two more strategies at play in these mergers as well, according to Blackburn. “One is to theoretically control the dollars, a lot of which is in extremely expensive chronic disease patients,” he says. “Secondarily, the players involved have less room to maneuver. You can’t move the needle if you’re buying a bunch of $5-million retail pharmacies. What does that do for you if you’re in the billions? It doesn’t mean you don’t do it, but it’s a small strategy compared to merging with Aetna.”

Also in the news last year was Amazon’s acquisition of PillPack. Both companies were tight-lipped on the details of the deal, which some published accounts pegged at $1 billion.

Blackburn was not surprised by the acquisition, which he characterized as a “supply chain play.” While Amazon-PillPack is totally different from the CVS-Aetna and Cigna-Express Scripts deals, there is a connection.

“There’s a lot of talk that the reason CVS and Aetna are teaming up and the reason Cigna and Express Scripts are teaming up is because Amazon is coming into the supply chain,” he explains.

Blackburn concludes that while it’s possible that 2019 will bring more super mergers and acquisitions, he doesn’t think we’ll come close to the kinds of numbers seen this year. Much more likely are smaller acquisitions like UnitedHealthcare’s purchase of Avella to build up its OptumRx pharmacy segment, which received little coverage in the business media.

“There are only a few mega deals to be done,” Blackburn predicts. “There are mid-tier PBMs out there, not a lot of them, but they’re out there. We saw Diplomat Pharmacy buy a PBM last year, and that put them in the PBM space. There’s certainly room for larger transactions, but not at this scale.”
2018 was an excellent year. It reported record revenues of $575.6 million for the first nine months, up 11.5% over the same period in 2017. It expects product bookings of between $645 and $670 million for this year.

“The major factor driving pharmacy automation is that the number of scripts is growing, and growing dramatically across all places of service. For our hospital and health system customers, pharmacy is 40% to 50% of their bottom line profit,” says Omnicell’s executive vice president and chief commercial officer Scott Seidelmann.

He adds that as health systems get bigger and their needs broaden, pharmacy is elevated in importance. “The impact that pharmacy has on the overall patient episode and its ability to influence not only patient care but economics across the continuum is driving the need for more automation,” he says.

Privately-held Innovation also reports considerable growth in 2018 for its PharmASSIST family of automation and process optimization solutions. It has hired 65 new employees and expects to add another dozen by the end of the year as it prepares to move into a new 91,000-square-foot office space in Johnson City, NY.

“We’ve seen a major move by the market for advancement in technology for centralized fulfillment of prescriptions. All pharmacy players that want to remain relevant are trying to provide an omnichannel experience for the pharmacy customer,” says Doyle Jensen, Innovation’s executive vice president of global business development.

While compressed margins and increased competition have resulted in less investment by independent pharmacists, Jensen identifies the addition of more specialized lines of services as an emerging trend. “Their investment in the last two or three years has been towards compliance-pack technology, like PillPack, where they can differentiate their service by doing something that the chains aren’t doing,” he notes. Independents with multiple retail locations are installing more advanced automated solutions that can leverage that scale, perhaps by creating a small central fill, he adds.

Pharmacy chains are beginning to move in the same direction as the agile independents, Jensen says, adding that a representative of a large chain in the Southeast recently told him that it’s only a matter of time before people get their prescriptions from Amazon, so the chain is investing in technology to keep those customers. “They know that once they’ve lost the customer, they’re probably not going to get them back. It’s a lot less expensive to retain customers than to attract them,” he points out.

As for the future challenges, Seidelmann cites the move toward more patients receiving treatment at home or lower-cost places of service instead of an acute care setting. “As that happens, we need to anticipate how we can deliver services and solutions to our customers to help them manage that trend,” he says. “We’ll certainly deliver solutions over the next few years that will help health systems manage this transition of care and maintain a continuity of care delivery with patients where they’re on the third floor of the ICU or at home and being treated by telemedicine.”

Telepharmacy

Telepharmacy has been transformed drastically in the last decade, and the prospects for future growth are bright. The telepharmacy market in the United States is predicted to reach $3.2 billion by 2020, or about 13% of the $22-billion telemedicine market.

Advancements in integrated technology and specialized software have optimized telepharmacy to the point where pharmacists working remotely can now handle many of the tasks that in-house pharmacists perform, freeing them up to focus on important clinical initiatives like medication reconciliation and discharge management that help ensure better patient outcomes.

Used widely by major pharmacy chains, telepharmacy has also been a solution for some rural areas that have lost their independent pharmacies, and for small to medium-sized hospitals that have difficulty recruiting staff pharmacists.
Telepharmacy is being optimized so that remote pharmacists can free up in-house pharmacists to focus on clinical initiatives that improve patient outcomes.

Brian Roberts, CEO at PipelineRx, says telepharmacy combines two important assets—technology and great pharmacists—enabled by access to the internet and sophisticated integration.

“We’re now cloud-based so the facilities don’t actually have to put any physical equipment in their hospital or facility,” he explains. “[Protected health information] security has gotten better so hospitals and community pharmacies are more confident that data is being protected. Prescription errors are lower because you get a very high-quality pharmacist who’s making the decisions, and they’re focused just on the patient and what’s going to be safe for them.”

With 30% of prescription processing in hospitals being done through some sort of telepharmacy, Roberts says there’s plenty of room for growth. He predicts that telepharmacy will continue to grow in 2019 as it plays an essential role in two specific areas: transition of care and expanding access to pharmacists.

PipelineRx launched its Discharge Management Program this year to handle patient transitions from hospital to nursing home or to home. “Thirty percent of those patients either have an error on their walking papers or they never get their medications filled,” he explains. “A lot of dollars are lost and a lot of people get sicker when they end up back in the hospital 30 days later because they didn’t get their meds filled.

Roberts notes that the pharmacist is the most trusted individual in the healthcare chain. PipelineRx plans to leverage that by establishing drug information lines that provide patients with direct access to a pharmacist who can answer their medication questions.

“Our vision is that patients and clinicians should have connections and access to a pharmacist anytime, anywhere. It’s going to only enhance patient safety and their satisfaction with their medication program,” he predicts.

Forty-five states now allow telepharmacy, although rules and requirements for operation vary widely. ASHP continues to advocate for its expanded use while acknowledging the regulatory purview of state boards of pharmacy.

“The intent of such regulations should be to balance protection of the public health with the increased patient access to the patient care services of pharmacists provided by telepharmacy,” says Christopher J. Topoleski, ASHP’s director of federal legislative affairs. “Although such regulations should allow for various arrangements across state borders and within or between health systems, these regulations all need to address a number of common concerns such as standards for the use of technicians in telepharmacy and the harmonization of the practice of pharmacy across state lines.”

Drug Prices

No discussion of pharmacy trends would be complete without a review of drug prices, whose sustained and dramatic escalation is considered by many to be one of the biggest threats to quality healthcare in this country.

Net-price spending on pharmaceuticals in the United States hit $324 billion in 2017, according to IQVIA statistics released earlier this year. In July, the Vizient Drug Price Forecast projected a weighted average drug price inflation rate of 4.92% for 2019, more than double the U.S. inflation rate. It attributes up to 80% of the total increase to high-dollar branded products that have no competition.

NCPA continues to call for a greater focus on the largely unregulated role of pharmacy benefit managers, and specifically retroactive pharmacy DIR fees, which it says are a top concern for independent community pharmacists.

“These retroactive clawbacks make it extremely difficult for community pharmacists to operate their...
small businesses. They also lead to inflated drug costs, which punish beneficiaries who use their drug plan to fill prescriptions,” Hoey says. The organization continues to work with officials at CMS, HHS, the White House, and Congress on the issue.

Action on drug pricing is not limited to the federal level, and many states are working to lower drug prices. “What we’re seeing is what we’ve suspected for years, [that] PBMs are reimbursing pharmacies low, charging Medicaid programs high, and more often than not, pocketing the difference,” Hoey explains, adding that Medicaid prescription payment reform will be a top advocacy priority for NCPA and many state pharmacy associations in 2019.

Vizient Senior Vice President for Pharmacy Services Dan Kistner, PharmD, is both optimistic and cautious about what lies ahead for drug prices in 2019, saying it could be a “game-changing year.” Eight pharmaceutical companies said they would freeze prices during 2018, but one, Pfizer, already announced it is raising prices in 2019.

Analysis from Rx Savings Solutions showed more than three dozen manufacturers raised prices on more than 1,000 drugs in the first week of January that resulted in an average 6% rise in drug prices.

But biosimilars could swing the pendulum the other way. The biosimilars market is growing, and the potential competition could quell the expense of biologics—including Humira, Remicade, and Neupogen—which account for almost 40% of all prescription drug spending. McKinsey reports that biosimilar sales could triple in size to $15 billion by 2020.

In mid-2018, the FDA released its Biosimilar Action Plan (BAP) and reaffirmed its commitment to encouraging innovation and competition among biologics and the development of biosimilars. To date, the agency has approved 14 biosimilar products.

“As the U.S. market continues to expand and evolve, economies of scale should allow biosimilars to pass on more savings to payers and, in turn, patients,” states BAP. “Prices should continue to fall as markets become more competitive.”

Also on the horizon (as it has been for the last two years) is the CREATES Act, aimed at reducing prices and increasing the competitiveness of generic drugs, which comprise 90% of all prescriptions in the United States. The Congressional Budget Office estimates the proposed legislation would save $3.8 billion over a 10-year period.

The bill was removed from the 2018 federal budget package after the pharmaceutical industry lobbied against it. “ASHP supports the CREATES Act, which would promote competition by limiting manufacturers’ ability to prevent potential competitors from entering the generic market,” says Topoleski. “We are optimistic that the bill, if not acted upon this year, will be reintroduced in the 116th Congress.”

One new entrant in the drug price wars that will be tested next year is Civica Rx, a not-for-profit generic drug company with the goal of addressing the shortages and high prices of lifesaving medications. Launched a year ago by five healthcare systems, it will be an FDA-approved manufacturer that will directly manufacture the drugs or subcontract them to reputable manufacturing organizations. Civica Rx plans to deliver 14 hospital-administered generic drugs to market in 2019.

“Serving patients is a privilege, and that privilege comes with significant responsibilities,” explains President and CEO Martin Van Trieste. “Some of those responsibilities are to deliver quality medicines and a robust and reliable supply chain at a fair and sustainable price. That’s the core of what we’re trying to do.”

Van Trieste uses the phrase “disruptive to the marketplace” to describe the company’s operating model, its production and distribution plans, and the fact that it will not pay rebates. But he also promises that Civica Rx will offer price transparency that is fair and sustainable, and that it will rely on built-in redundancies in manufacturing and their supply chain, plus significant safety stock, to ensure that there will be no drug shortages.

“If people know that if they drop the ball Civica is there to stand up and take it away from them, that’s a policing function in the marketplace,” Van Trieste says.

He says initial response to Civica Rx has been overwhelming, with close to 150 hospital systems expressing very strong interest to date.

Finally, The Braff Group’s Blackburn says with gross margins at the pharmacy level squeezed to the max, it’s time for bigger players to exercise their power to control drug costs. “There is an opportunity for companies like Express Scripts and Cigna, Aetna/CVS, UnitedHealthcare and Optum, and Medicare and Medicaid to start more aggressively directing which drugs are going to be in their formularies and how the drugs are going to be paid for,” he concludes. DT

Beth Longware Duff is a contributing editor.
Overall adverse event rates were similar across treatment groups

- Numerically more serious adverse events related to bleeding; overall rates were low (2.7% for VASCEPA vs 2.1% for placebo, \(P=0.06\)), with no fatal bleeding observed in either group and no significant increase in adjudicated hemorrhagic stroke or serious central nervous system or gastrointestinal bleeding
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Please see accompanying Brief Summary of full Prescribing Information or go to www.vascepahcp.com.
FDA-APPROVED INDICATION AND LIMITATIONS OF USE FOR VASCEPATM

- VASCEPATM ([icosapent ethyl]) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adults with severe (>500 mg/dL) hypertriglyceridemia
- In patients with severe hypertriglyceridemia, the effect of VASCEPA on cardiovascular mortality or morbidity or on the risk of pancreatitis has not been determined

IMPORTANT SAFETY INFORMATION FOR VASCEPA FROM FDA-APPROVED LABEL

Data from Two 12-Week Studies [MARINE and ANCHOR] of Patients with Triglycerides Values of 200 to 2000 mg/dL [n=622 on VASCEPA, n=309 on placebo]1
- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy
- Use with caution in patients with known hypersensitivity to fish and/or shellfish
- The most common reported adverse reaction (incidence >2% and greater than placebo was arthralgia (2.3% VASCEPA, 1.0% placebo)
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088
- Patients receiving treatment with VASCEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically
- Patients should be advised to swallow VASCEPA capsules whole; not to break open, crush, dissolve, or chew VASCEPA

IMPORTANT INFORMATION FOR HCPs ABOUT VASCEPATM ([ICOSAPENT ETHYL]) CAPSULES

IMPORTANT NEW INFORMATION: REDUCE-IT™ CARDIOVASCULAR OUTCOMES STUDY OF VASCEPATM2,3

The effects of VASCEPA on the prevention of cardiovascular events was evaluated in a multi-center, double-blind, randomized, placebo-controlled, event-driven trial (REDUCE-IT, NCT01492361) in 8,179 adult patients at low-density lipoprotein cholesterol (LDL-C) goal, with established cardiovascular disease (CVD) or at high risk for CVD, and hypertriglyceridemia (fasting triglyceride [TG] >135 and <500 mg/dL). Patients were eligible to enter the trial if they were at least 65 years of age and on stable statin therapy with fasting LDL-C levels of >40 and <100 mg/dL and fasting TG levels of >135 and <500 mg/dL. Patients also needed to have either established CVD (secondary prevention cohort), defined as documented history of coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease, or be at least 50 years of age with diabetes and at least one additional risk factor (primary prevention cohort).

- Key exclusion criteria included severe heart failure, active severe liver disease, homoglobin A1c >10.0%, planned coronary intervention or surgery, history of acute or chronic pancreatitis, and known hypersensitivity to fish, shellfish, or ingredients of VASCEPA or placebo.

- 70.7% of patients were enrolled based on having established CVD (secondary prevention cohort), 29.3% were enrolled based on being at high risk for CVD (primary prevention cohort).
- Patients were randomly assigned 1:1 to receive either VASCEPA (4 grams daily) or placebo (4089 VASCEPA, 4090 placebo).
- The median follow-up duration was 58 months (4.9 years).
- Overall, 99.8% of patients were followed until the end of the trial or death.
- The median age at baseline was 64 years (range: 44 years to 92 years), with 46% being at least 65 years old; 28.8% were women.
- The trial population was 90.2% White, 1.9% Black, and 5.5% Asian; 4.2% identified as Hispanic ethnicity.
- Regarding prior diagnoses of cardiovascular disease, 44.7% had prior myocardial infarction, 6.1% prior unknown stroke or transient ischemic attack (TIA), and 9.2% had symptomatic peripheral arterial disease.
- Selected additional baseline risk factors included hypertension (36.6%), diabetes mellitus (0.7% type 1; 57.8% type 2), current daily cigarette smoking (15.2%), New York Heart Association class I or II congestive heart failure (17.7%), and eGFR < 60 mL/min per 1.73 m2 (22.2%).
- Patients enrolled were treated with statin therapy at baseline with most (93.2%) on a high- (30.8%) or moderate-intensity (62.5%) statin therapy, and 4.4% were also taking ezetimibe at baseline.
- Most patients at baseline were taking at least one other cardiovascular medication including anti-platelet agents (79.4%), beta blockers (70.7%), angiotensin converting enzyme (ACE) inhibitors (51.9%), or angiotensin receptor blockers (27.0%).
- On stable background lipid-lowering therapy, the median [Q1, Q3] LDL-C at baseline was 75.0 [62.0, 89.0] mg/dL; the mean [SD] was 76.2 [20.3] mg/dL.
- On stable background lipid-lowering therapy, the median [Q1, Q3] fasting TG was 216.0 [176.0, 272.5] mg/dL; the mean [SD] was 232.3 [80.1] mg/dL.

The primary results from REDUCE-IT are shown in the Table below (see CONDUCT OF REDUCE-IT AND ANALYSIS AND REVIEW OF REDUCE-IT DATA).

Effect of VASCEPA on Cardiovascular Events in Patients with Established CVD or at High Risk for CVD with Statin-treated Triglycerides >135 and <500 mg/dL in REDUCE-IT

<table>
<thead>
<tr>
<th></th>
<th>Placebo N = 6090 n (%)</th>
<th>VASCEPA N = 6089 n (%)</th>
<th>VASCEPA vs Placebo Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to first occurrence of cardiovascular death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACES)</td>
<td>901 [22.0]</td>
<td>705 [17.2]</td>
<td>0.75 [0.68 - 0.83]</td>
</tr>
<tr>
<td>Time to first occurrence of cardiovascular death, myocardial infarction, stroke (5-point MACES)</td>
<td>406 [14.8]</td>
<td>459 [11.2]</td>
<td>0.74 [0.65 - 0.83]</td>
</tr>
<tr>
<td>Time to cardiovascular death</td>
<td>213 [5.2]</td>
<td>174 [4.3]</td>
<td>0.80 [0.64 - 0.98]</td>
</tr>
<tr>
<td>Time to death by any cause</td>
<td>310 [7.6]</td>
<td>274 [5.7]</td>
<td>0.87 [0.74 - 1.02]</td>
</tr>
<tr>
<td>Time to first fatal or non-fatal myocardial infarction</td>
<td>355 [8.7]</td>
<td>250 [4.1]</td>
<td>0.59 [0.54 - 0.81]</td>
</tr>
<tr>
<td>Time to first fatal or non-fatal stroke</td>
<td>134 [3.3]</td>
<td>98 [2.4]</td>
<td>0.72 [0.55 - 0.93]</td>
</tr>
<tr>
<td>Time to first emergent or urgent coronary revascularization</td>
<td>321 [7.8]</td>
<td>214 [5.3]</td>
<td>0.65 [0.55 - 0.78]</td>
</tr>
<tr>
<td>Time to first coronary revascularization</td>
<td>544 [13.3]</td>
<td>374 [9.2]</td>
<td>0.44 [0.38 - 0.52]</td>
</tr>
<tr>
<td>Time to first hospitalization for unstable angina</td>
<td>157 [3.8]</td>
<td>108 [2.4]</td>
<td>0.68 [0.53 - 0.87]</td>
</tr>
</tbody>
</table>

All prespecified individual and composite endpoints were statistically significant except time to death by any cause.
1. Time to death by any cause, or total mortality, is not a component of either the primary composite endpoint or key secondary endpoint.
2. The predefined composite secondary endpoint included emergent or urgent revascularization, the composite of all revascularization was predefined as a tertiary endpoint.
3. Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

VASCEPA significantly reduced the following:
- the risk for the primary composite endpoint (5-point MACES; time to first occurrence of cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, or coronary revascularization; p<0.001), and
- the key secondary composite endpoint [3-point MACES; time to first occurrence of cardiovascular death, myocardial infarction, or stroke; p<0.001].

Prespecified hierarchical testing of other secondary endpoints revealed significant reductions in the following:
- cardiovascular death (p=0.03),
- fatal or nonfatal myocardial infarction (p<0.001),
- fatal or nonfatal stroke (p=0.01),
- emergent or urgent coronary revascularization (p<0.001), and
- hospitalization for unstable angina (p=0.002).

The benefits of VASCEPA were seen on a background of predominantly (93.2%) moderate- to high-intensity statin use and median baseline LDL-C levels of 75.0 mg/dL.
The Kaplan–Meier estimates of the cumulative incidence of the primary and key secondary composite endpoints over time are shown in Figure 1 and Figure 2 below.

**Figure 1. Estimated Cumulative Incidence of Primary Composite Endpoint Over 5 Years in REDUCE-IT**

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Placebo</th>
<th>VASCEPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>4090</td>
<td>3743</td>
<td>3327</td>
</tr>
<tr>
<td>2897</td>
<td>2347</td>
<td>1358</td>
</tr>
<tr>
<td></td>
<td>4089</td>
<td>3787</td>
</tr>
<tr>
<td></td>
<td>3431</td>
<td>2951</td>
</tr>
<tr>
<td></td>
<td>2531</td>
<td>2533</td>
</tr>
<tr>
<td></td>
<td>1430</td>
<td></td>
</tr>
</tbody>
</table>

Cl denotes confidence interval. Curves were visually truncated at 5.7 years due to a limited number of events beyond that point in time; all patient data were included in analyses.

**Figure 2. Estimated Incidence of Key Secondary Composite Endpoint Over 5 Years in REDUCE-IT**

<table>
<thead>
<tr>
<th>No. at Risk</th>
<th>Placebo</th>
<th>VASCEPA</th>
</tr>
</thead>
<tbody>
<tr>
<td>4090</td>
<td>3837</td>
<td>3500</td>
</tr>
<tr>
<td>3002</td>
<td>2542</td>
<td>1487</td>
</tr>
<tr>
<td></td>
<td>4089</td>
<td>3861</td>
</tr>
<tr>
<td></td>
<td>3565</td>
<td>3115</td>
</tr>
<tr>
<td></td>
<td>2981</td>
<td>1562</td>
</tr>
</tbody>
</table>

Cl denotes confidence interval. Curves were visually truncated at 5.7 years due to a limited number of events beyond that point in time; all patient data were included in analyses.

The difference between VASCEPA and placebo in median percent change in TG from baseline to Month 4 was -20.1 [p<0.001] and from baseline to Month 12 was -19.7 [p<0.001]. At Month 12, the median [Q1, Q3] TG was 175.0 [132.0, 238.0] mg/dl in the VASCEPA group, with 25.9% of patients having TG <150 mg/dl and 61.3% having a TG <200 mg/dl. The difference between VASCEPA and placebo in median percent change in LDL-C from baseline to Month 12 was -6.6% [p<0.001]. At Month 12, the median [Q1, Q3] LDL-C was 77.0 [63.0, 94.0] mg/dl in the VASCEPA group, with 25.5% of patients having LDL-C <70 mg/dl and 79.9% having LDL-C <100 mg/dl.

**Important Safety Information for VASCEPA from REDUCE-IT (n=4089 on VASCEPA, n=4090 on placebo)**

- Patients were exposed to VASCEPA or placebo for a median of 58 months; 86.9% of patients were exposed for ≥12 months, 77.2% were exposed for >12 months, 64.8% were exposed for ≥36 months, 53.6% were exposed for ≥48 months, 39.5% were exposed for >60 months, and 0.1% were exposed for ≥72 months.
- Overall adverse event rates were similar across treatment groups.
  - Adverse events and serious adverse events leading to study drug discontinuation were similar to placebo.
  - The one serious adverse event that occurred at a frequency of at least 2% was pneumonia (2.6% in the VASCEPA group and 2.9% in the placebo group, P=0.42).

**Treatment-Emergent Adverse Events**

<table>
<thead>
<tr>
<th></th>
<th>VASCEPA</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with at Least One TEAE</td>
<td>3343 (81.8)</td>
<td>3326 (81.3)</td>
</tr>
<tr>
<td>TEAE</td>
<td>1252 (30.6)</td>
<td>1254 (30.7)</td>
</tr>
<tr>
<td>TEAE Leading to Withdrawal of Study Drug</td>
<td>321 (7.9)</td>
<td>335 (8.2)</td>
</tr>
<tr>
<td>TEAE Leading to Withdrawal of Study Drug</td>
<td>88 (2.2)</td>
<td>88 (2.2)</td>
</tr>
<tr>
<td>TEAE Leading to Death</td>
<td>94 (2.3)</td>
<td>102 (2.5)</td>
</tr>
</tbody>
</table>

Note: Treatment-emergent adverse event (TEAE) is defined as an event that first occurs or worsens in severity on or after the date of beginning study drug and within 30 days after the completion or withdrawal from study. Percentages are based on the number of patients randomized to each treatment group in the Safety population. Events that were positively adjudicated as clinical endpoints are not included.

**Adverse events occurring in 5% of VASCEPA patients and statistically more frequently with VASCEPA than placebo**

- Peripheral edema (6.5% VASCEPA patients versus 5.0% placebo patients)
  - There was no significant difference in the prespecified adjudicated tertiary endpoint of new congestive heart failure, which occurred in 4.1% of VASCEPA patients versus 4.3% of placebo patients.
- Constipation (5.4% VASCEPA patients versus 3.6% placebo patients)
- Atrial fibrillation (5.3% VASCEPA patients versus 3.9% placebo patients)
  - This adverse event finding is consistent with an increase in the prespecified adjudicated tertiary endpoint of atrial fibrillation or flutter requiring hospitalization, which occurred in 3.1% of VASCEPA patients versus 2.1% of placebo patients (P=0.004).
- The rate of treatment-emergent serious adverse events for bleeding was 2.7% in the VASCEPA group versus 2.1% in the placebo group, with a nonsignificant, but trending p-value of 0.06.
- There were none.

- No fatal bleeding events in either group,
- No significant increases in adjudicated hemorrhagic stroke (0.3% in VASCEPA patients versus 0.2% in placebo patients; P=0.55),
- No significant serious central nervous system bleeding (0.3% versus 0.2%; P=0.42),
- No significant gastrointestinal bleeding (1.5% versus 1.1%; P=0.15).

**Mineral oil placebo consideration and analysis**

In REDUCE-IT, a placebo containing mineral oil was used to mimic the color and consistency of the drug studied. No strong evidence for biological activity of the same mineral oil was identified in connection with FDA approval of VASCEPA in July 2012 based on the MARINE phase 3 clinical trial, in connection with FDA review of the ANCHOR phase 3 clinical trial, or after several years of quarterly review by the Data Monitoring Committee (DMC) for REDUCE-IT after FDA requested that the DMC periodically assess unblinded lipid data to monitor for signals that the placebo might not be inert. While the DMC noted variation in LDL-C measurements in both arms and that a small physiological effect of mineral oil might be possible, the DMC concluded that it was not possible to determine if the LDL-C increase in the placebo arm was a natural increase over time or due to the mineral oil, they found no apparent effect on outcomes and found that this small change was unlikely to explain the observed benefit of VASCEPA over placebo.

Each of the three VASCEPA clinical trials, MARINE, ANCHOR and REDUCE-IT, was conducted under a special protocol, or SPA, agreement with FDA in which mineral oil was agreed with FDA as an acceptable placebo.
As published within the main presentation of the REDUCE-IT results (Bhatt DL, Steg PG, Miller M, et al. N Engl J Med 2018.), at baseline, the median LDL-C was 75.0 mg/dL. The median change in LDL-C was 3.1% [–2.0 mg/dL] for VASCEPA and 10.2% [+7.0 mg/dL] for the mineral oil placebo arm; placebo-corrected median change from baseline of -6.6% [-5.0 mg/dL; p < 0.001]. If mineral oil in the placebo might have affected statin absorption in this small sample, this might have contributed to differences in outcomes between the groups. However, the relatively small differences in LDL-C levels between groups would not be likely to explain the 25% risk reduction observed with VASCEPA, and a post hoc analysis suggested a similar lower risk regardless of whether there was an increase in LDL-C level among the patients in the placebo group. Although open label, Japan EPA Lipid Intervention Study (JELIS) previously demonstrated a 19% risk reduction without a mineral oil placebo.

CONDUCT OF REDUCE-IT AND ANALYSIS AND REVIEW OF REDUCE-IT DATA

FDA has not reviewed and opined on a supplemental new drug application related to REDUCE-IT. FDA has thus not reviewed the information herein or determined whether to approve VASCEPA for use to reduce the risk of major adverse cardiovascular events in the REDUCE-IT patient population.*

REDUCE-IT results were first presented at the 2018 Scientific Sessions of the American Heart Association (AHA) on November 10, 2018 in Chicago, Illinois and concurrently published online in The New England Journal of Medicine (NEJM).*

REDUCE-IT was sponsored by Amarin Pharma, Inc. and its affiliates and conducted under a special protocol agreement with FDA.

- The REDUCE-IT steering committee, consisting of academic physicians, and Amarin representatives developed the protocol (Bhatt DL, Steg PG, Miller M, et al. N Engl J Med 2018.) and were responsible for the conduct and oversight of the study, and data interpretation.
- The primary, secondary, and tertiary adjudicated endpoint analyses were validated by the data monitoring committee independent statistician.

Further REDUCE-IT data assessment and data release could yield additional useful information to inform greater understanding of the trial outcome:

- Further detailed data assessment by Amarin and regulatory authorities will continue and take several months to complete and record
- The final evaluation of the totality of the efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations:
  - New information affecting the degree of treatment benefit on studied endpoints
  - Study conduct and data robustness, quality, integrity and consistency
  - Additional safety data considerations and risk/benefit considerations
  - Consideration of REDUCE-IT results in the context of other clinical studies

VASCEPA may not be eligible for reimbursement under government healthcare programs (such as Medicare and Medicaid) and certain commercial plans to reduce the risk of major adverse cardiovascular events in the REDUCE-IT patient population. We encourage you to check that for yourself.

IMPORTANT INFORMATION FOR HCPs ABOUT CONTINUED UNCERTAINTY AROUND THE BENEFIT, IF ANY, OF LOWERING TG LEVELS AFTER STATIN THERAPY IN PATIENTS WITH HIGH (200–499 mg/dL) TG LEVELS

- In REDUCE-IT, cardiovascular benefits appeared similar across baseline levels of triglycerides (less than 150 mg/dL, 150 to 199 mg/dL, and 200 mg/dL or greater).
  - Additionally, the reduction in major adverse cardiovascular events with VASCEPA appeared to occur irrespective of an achieved triglyceride level above or below 150 mg/dL at one year, suggesting that the cardiovascular risk reduction was not tied to achieving a normal triglyceride level.

These observations suggest that at least some of the impact of VASCEPA on the reduction in ischemic events may be explained by metabolic effects other than triglyceride lowering.

- VASCEPA is not FDA-approved to lower TG levels in statin-treated patients with mixed dyslipidemia and persistent high [≥200 mg/dL and <500 mg/dL] TG levels due to current uncertainty regarding the benefit, if any, of drug-induced changes in lipid/lipoprotein parameters beyond statin-lowered LDL-C on cardiovascular risk among statin-treated patients with residually high TG.
- Other cardiovascular outcomes trials (ACCORD Lipid, AIM-HIGH, and HPS2-THRIVE), while not designed to test the effect of lowering TG levels in patients with high TG levels after statin therapy, each failed to demonstrate incremental cardiovascular benefit of adding a second lipid-altering drug (fenofibrate or formulations of niacin), despite raising HDL-C and reducing TG levels, among statin-treated patients with well-controlled LDL-C.

Other cardiovascular outcomes trials that studied fish oil or mixtures of omega-3 acids that include the omega-3 acid, DHA, have reported negligible impact on cardiovascular events.

No head-to-head, randomized, well-controlled studies have been conducted to compare the effects of VASCEPA with other FDA-approved TG-lowering therapies.

POTENTIAL MECHANISMS OF ACTION

Mechanisms responsible for the benefit shown in REDUCE-IT were not the focus of REDUCE-IT, but the ranked samples and array of biomarkers measured leave room for mechanistic insights through future analyses. Potential mechanisms discussed in Bhatt DL, Steg PG, Miller M, et al. N Engl J Med 2018., include TG reduction, anti-thrombotic effects, antiplatelet or anticoagulant effects, membrane-stabilizing effects, effects on stabilization and/or regression of coronary plaque and inflammation reduction. More study is needed to determine to what extent, if any, these effects or others may be responsible for the CV risk reduction benefit demonstrated with use of VASCEPA in REDUCE-IT.

*This information is intended to ensure Amarin meets its continuing obligation to update healthcare professionals regarding off-label use of VASCEPA to assure that its communications remain truthful and non-misleading, consistent with the federal court approved settlement under Amarin Pharma, Inc. et al. v. United States Food and Drug Administration et al., 119 F.Supp.3d 196, 236 (S.D.N.Y. 2015).

VASCEPA® (icosapent ethyl) Capsules, for oral use
Brief summary of Prescribing Information
Please see Full Prescribing Information for additional information about VASCEPA®.

1 INDICATIONS AND USAGE
VASCEPA® (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia. Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet and exercise regimen before receiving VASCEPA and should continue this diet and exercise regimen with VASCEPA.

Attempts should be made to control any medical problems such as diabetes mellitus, hypothyroidism, and alcohol intake that may contribute to lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed, if possible, prior to consideration of TG-lowering drug therapy.

Limitations of Use: The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

2 DOSAGE AND ADMINISTRATION
Assess lipid levels before initiating therapy. Identify other causes (e.g., diabetes mellitus, hypothyroidism, or medications) of high triglyceride levels and manage as appropriate. [see Indications and Usage (1)].

Patients should engage in appropriate nutritional intake and physical activity before receiving VASCEPA, which should continue during treatment with VASCEPA.

The daily dose of VASCEPA is 4 grams per day taken as either: four 0.5-g capsules twice daily with food, or as two 1-g capsules twice daily with food.

Patients should be advised to swallow VASCEPA capsules whole. Do not break open, crush, dissolve, or chew VASCEPA.

4 CONTRAINDICATIONS
VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.

5 WARNINGS AND PRECAUTIONS
5.1 Monitoring: Laboratory Tests
In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy with VASCEPA.

5.2 Fish Allergy
VASCEPA contains fish icosapentaenoic acid (EPA), obtained from the oil of fish. It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to VASCEPA. VASCEPA should be used with caution in patients with known hypersensitivity to fish and/or shellfish.

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse reactions reported in at least 2% and at a greater rate than placebo for patients treated with VASCEPA based on pooled data across two clinical studies are listed in Table 1.

Table 1. Adverse Reactions Occurring at Incidence ≥2% and Greater than Placebo in Double-Blind, Placebo-Controlled Trials*

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=309)</th>
<th>VASCEPA (N=622)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthralgia</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>2.3</td>
</tr>
</tbody>
</table>

*Studies included patients with triglyceride values of 200 to 2000 mg/dL.

An additional adverse reaction from clinical studies was oropharyngeal pain.

7 DRUG INTERACTIONS
7.1 Anticoagulants
Some published studies with omega-3 fatty acids have demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in those studies has not exceeded normal limits and did not produce clinically significant bleeding episodes. Patients in clinical trials with VASCEPA and other drugs affecting coagulation (e.g., antiplatelet agents) should be monitored periodically.

7 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. It is unknown whether VASCEPA can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. VASCEPA should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.

In pregnant rats given oral gavage doses of 0.3, 1, and 2 g/kg/day icosapent ethyl from gestation through organogenesis all drug treated groups had visceral or skeletal abnormalities including: 13% reduced ribs, additional liver lobes, testes medially displaced and/or not descended at human systemic exposures following a maximum oral dose of 4 g/day based on body surface area comparisons. Variations including incomplete or abnormal ossification of various skeletal bones were observed in the 2 g/kg/day group at 5 times human systemic exposure following an oral dose of 4 g/day based on body surface area comparison.

In a multigenerational developmental study in pregnant rats given oral gavage doses of 0.3, 1, 3 g/kg/day ethyl-EPA from gestation day 7-17, an increased incidence of absent optic nerves and unilateral testes atrophy were observed at ≥30.3 g/kg/day at human systemic exposure following an oral dose of 4 g/day based on body surface area comparisons across species. Additional variations consisting of early incisor eruption and increased percent cervical ribs were observed at the same exposures. Pups from high dose treated dams exhibited decreased copulation rates, delayed estrus, decreased implantations and decreased surviving fetuses (F2) suggesting multigenerational effects of ethyl-EPA at 7 times human systemic exposure following 4 g/day dose based on body surface area comparisons across species.

In pregnant rabbits given oral gavage doses of 0.1, 0.3, and 1 g/kg/day from gestation through organogenesis there were increased dead fetuses at 1 g/kg/day secondary to maternal toxicity (significantly decreased food consumption and body weight loss).

In pregnant rats given ethyl-EPA from gestation day 17 through lactation day 20 at 0.3, 1, 3 g/kg/day complete litter loss was observed in 2/23 litters at the low dose and 1/23 mid-/dose dams by postnatal day 4 at human exposures based on a maximum dose of 4 g/day comparing body surface area exposures across species.

8.3 Nursing Mothers
Studies with omega-3-acid ethyl esters have demonstrated excretion in human milk. The effect of this excretion on the infant of a nursing mother is unknown: caution should be exercised when VASCEPA is administered to a nursing mother. An animal study in lactating rats given oral gavage 1% ethyl-EPA demonstrated that drug levels were 6 to 14 times higher in milk than in plasma.

8.4 Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use
Of the total number of subjects in clinical studies of VASCEPA, 33% were 65 years of age and over. There were no overall differences in safety or effectiveness between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

9 DRUG ABUSE AND DEPENDENCE
VASCEPA does not have any known drug abuse or withdrawal effects.

11 NONCLINICAL TOXICOLOGY
11.1 Carcinogenicity, Mutagenesis, Impairment of Fertility
In a 2-year rat carcinogenicity study with oral gavage doses of 0.09, 0.27, and 0.91 g/kg/day icosapent ethyl, respectively, males did not exhibit drug-related neoplasms. Hemangiomias and hemangiomas of the mesenteric lymph node, the site of drug absorption, were observed in females at clinically relevant exposures based on body surface area comparisons across species relative to the maximum clinical dose of 4 g/day. Overall incidence of hemangiomias and hemangiomas in all vascular tissues did not increase with treatment.

In a 6-month carcinogenicity study in Tg ralte2 transgenic mice with oral gavage doses of 0.5, 1.2, and 4.6 g/kg/day icosapent ethyl, drug-related incidences of benign squamous cell papilloma in the skin and subcutis of the tail was observed in high dose male mice. The papillomas were considered to develop secondary to chronic irritation of the proximal tail associated with focal excretion of oil and therefore not clinically relevant. Drug-related neoplasms were not observed in female mice.

Icosapent ethyl was not mutagenic with or without metabolic activation in the bacterial mutagenesis (Ames) assay or in the in vitro mouse micronucleus assay. A chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells was positive for clastogenicity with and without metabolic activation.

In an oral gavage rat fertility study, ethyl-EPA administered at doses of 0.3, 1, and 3 g/kg/day to male rats for 9 weeks before mating and to female rats for 14 days before mating through day 7 of gestation, increased anogenital distance in female pups and increased cervical ribs were observed at 3 g/kg/day (7 times human systemic exposure with 4 g/day clinical dose based on a body surface area comparison).

17 PATIENT COUNSELING INFORMATION
17.1 Information for Patients
See VASCEPA Full Package Insert for Patient Counseling Information

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Pharmacist-Driven Intervention Program Reduces Readmissions

Study validates benefits of pharmacists on healthcare teams

“When a pharmacist is deployed with a structured intervention as a part of the multidisciplinary discharge process, readmissions can be reduced.”

Deborah Hauser, RPh

A pharmacist-driven intervention program can reduce readmissions, according to a study published in the American Journal of Health-System Pharmacy.

Rates of 30-day readmissions were substantially lower with pharmacist involvement and collaboration with other healthcare team members during patient transitions from the hospital to home, according to the study.

Deborah Hauser, RPh, MHA, network director of pharmacy, outpatient pharmacy, Einstein Medical Center, and her colleagues conducted a quality-improvement cohort study of 1,059 admissions of 667 patients at an inner-city hospital. Einstein is the largest independent academic medical center in the Philadelphia area.

The study compared rates of unplanned readmissions within 30 days of discharge in the full- and partial-intervention groups and in patients who received standard discharge care.

Among patients who received the full intervention, 30 of 305 admissions (9.8%) resulted in unplanned readmissions within 30 days, compared with a readmission rate of 20.4% (110 of 538 patients) among patients who received standard discharge care.

The findings demonstrate the role and value of pharmacists in reducing hospital readmissions using a standard intervention that includes medication reconciliation, patient-centered education, resolution of access-to-care issues, and follow-up counseling and communication with healthcare providers, says Hauser.

“Pharmacists are best suited to review and optimize patient therapies to improve patient care outcomes, Hauser says. “Pharmacists play very close attention to medication details to ensure an optimal discharge for the patient as it pertains to medication therapy management beyond the hospital as part of a larger population health strategy.”

Pharmacists are often underutilized in hospitals, according to Hauser. “There is tremendous opportunity to improve the discharge process and continue to build on the use of pharmacists to improve medication therapy management beyond the hospital as part of a larger population health strategy.”

Einstein Medical Center is developing a role for pharmacists in an accountable care organization as a follow-up expansion to its current program.

Tracey Walker is content manager of Drug Topics’ sister publication, Managed Healthcare Executive.
Chronic Kidney Disease (CKD) is a spectrum of conditions characterized by a progressive loss of kidney function. Thirty million Americans have some form of CKD, and millions more run the risk of developing it. Protecting and preserving kidney function can be an undertaking, as many medications are either cleared by the kidneys or alter kidney function. In dialysis patients, some drugs may dialyze out if administered prior to dialysis. But successfully managing this patient population transcends the intricacies of patient individuality and pharmacokinetics and must acknowledge that patients lack of awareness regarding the full spectrum of the condition.

“Kidney disease is very common, and often people who have it don’t necessarily know they have it because they don’t have symptoms until it’s quite advanced. In fact, many people don’t feel bad until they approach end-stage kidney disease,” says Kevin Erickson, MD, assistant professor medicine at Baylor College of Medicine.

Kidney Function
Impaired kidney function affects other areas of the body, making monitoring exceedingly important. The kidneys play an important role in maintaining homeostasis in the body by regulating the extracellular fluid volume, one of the body’s natural buffering systems, and the body’s internal pH; governing ion concentrations; equilibrating the body’s osmolarity; excreting waste and other unwanted substances; and producing and activating hormones, including renin and erythropoietin. Anything that impairs kidney function can compromise the kidney’s ability to execute these critical tasks.

Choosing Medications and Doses
Different stages of kidney damage are defined by the rate at which the glomeruli of the kidney filter blood, the glomerular filtration rate (GFR). A GFR of 90 ml/min is classified as a stage 1 kidney disease with normal function while lower GFR values correspond to worsening kidney function. The most severe form of kidney disease—kidney failure—results in severe or near-complete loss of kidney function. According to Erickson, kidney function changes over time, so medications—especially those cleared by the kidneys—may require adjustments if taken for long periods.

From a pharmacological standpoint, the kidneys are one of the mechanisms by which the body clear drugs, so as kidney function declines, some drugs will accumulate within the body. Dose adjustments may involve decreasing the dose and dosing frequency for medications that are cleared renally. For example, an antibiotic typically dosed twice a day might need to be administered at half the dose and only once a day in a patient with reduced kidney function. Additionally, certain medications can cause additional kidney damage in some patients who are already renally compromised.

Monitoring Function
Vicky Lewis, RPh, BCOP, a clinical pharmacy specialist in kidney transplantation at Texas Health Harris Methodist Hospital in Fort Worth says that patients with CKD should have their kidney function monitored for creatinine levels and creatinine clearance/estimated GFR (eGFR). Medication doses should be adjusted based on altered pharmacokinetics, and considering the effects of drug removal by dialysis. Additionally, certain medications should be used with caution or are contraindicated in CKD patients, she says.

Another crucial component of patient monitoring includes monitoring lab values for hyperphosphatemia, hypocalcemia, vitamin D deficiency, and secondary hyperparathyroidism—all of which may occur with CKD.

Because declining function hinders the kidneys’ ability to produce red blood cells, anemia can be common in CKD patients. Iron deficiency also contributes to the problem, but Lewis cautions that oral iron supplementation is rarely effective in CKD patients. Patients may need nutritional supplementation with a multivitamin specially formulated for CKD patients.

“Many standard multivitamins contain higher than recommended quan-
tities of vitamins A and C,” Lewis says. Standard multivitamins may also have electrolytes that may be restricted in CKD patients, such as potassium and phosphorus.

**Dialysis and Transplant**

Some medications are dialyzed out and must be administered after the patient receives dialysis. “We have to think about whether dialysis removes the medications,” Erickson says. “Some medications need to be given as supplements, and generally, these are smaller molecules that aren’t protein-bound.”

Patients with advanced kidney disease typically receive erythropoietin stimulating agent and activated vitamin D. While some kidney patients may receive oral vitamin D, dialysis patients typically receive vitamin D injections.

Kidney transplant recipients have an additional layer of complexity to consider. A transplanted kidney typically responds similarly to a healthy native kidney, but Breena Kane, PharmD, BCPS, a clinical pharmacy specialist in organ transplantation at the University of Chicago Medicine, stresses the importance of including kidney function when prescribing, dosing, and administering medications for these patients.

**Diet**

Dietary restrictions for patients with limited function and for some transplant recipients must also be considered. Kane says these dietary modifications vary per individual and largely depend on the individual’s kidney function and electrolyte balance. In such cases, CKD may not be the only factor that can disrupt electrolyte levels.

“Phosphorus is an interesting example [of electrolyte imbalance], as some patients with normal kidney function after transplant and persistent secondary hyperparathyroidism may have hypophosphatemia or low blood levels requiring increased dietary phosphorus intake,” says Joseph Vassalotti, M.D., chief medical officer for the National Kidney Foundation. Conversely, transplant recipients with low levels of kidney function, generally below an eGFR of 30 ml/1.73 m², may develop hyperphosphatemia. These patients must restrict dietary phosphorus.

Certain medications, such as ACE inhibitors and calcineurin inhibitors used in CKD, can spike potassium levels, mandating a low-potassium diet. Additionally, calcineurin’s significant drug interactions can further complicate a patient’s medication regimen, creating an additional opportunity for pharmacist intervention.

“The intensity of drug interactions may lead us to avoid certain medications, if able, and pick medications with lower interaction potential,” Kane says. “We are generally careful with medications that have nephrotoxic potential following kidney transplant, but use them with close monitoring if the benefit outweighs the risks.”

Kane cites her preference for an integrate inhibitor-based antiretroviral regimen for an HIV transplant patient over a protease-based inhibitor regimen as an example. She also recommends avoiding NSAIDs in transplant patients to avoid the potential for hemodynamic kidney injury. Pharmacists working with CKD patients post-transplantation must use care when combining the patient’s post-transplant medication regimen with other medications that may exhibit myelosuppressive effects because of additive toxicities.

**Patient Education**

“Ensuring patients are compliant with their phosphate binders, calcium supplementation, vitamin D supplementation, and calcimimetics is critical for prevention of renal bone disease,” Lewis says.

Motivating patients to adopt dietary restriction of phosphorus is also important. Lewis says patient adherence to phosphate binder and a phosphate-restrictive diet is low, which she attributes to patients not understanding the consequences of too much phosphorus.

Managing CKD—regardless of the stage—is a challenge, but Kane says ensuring optimal outcomes includes managing much more than the CKD itself.

“I think the most challenging issue is the complexity of the CKD patient population,” she states, pointing out the prevalence of comorbidities and complicated drug regimens among CKD patients. “Pharmacists can help the team holistically address these comorbidities, provide patient education, and remove barriers to adherence.”

While the pharmacist’s role in CKD management may not be the complete solution for CKD patients, incorporating pharmacists in their care is definitely a step in the right direction.

Frieda Wiley, PharmD, is a regular contributor.
Joe Halfpap, PharmD, always knew he wanted to work directly with patients. He pursued a residency in emergency pharmacy immediately after pharmacy school and is now a clinical pharmacist in emergency medicine at University of Wisconsin Hospitals and Clinics in Madison.

But it was an experience during his emergency department rotation in the second year of his pharmacy residency that proved his career choice was right. He saw a cardiac patient’s response to a half-milligram of epinephrine, an inappropriate dose for the patient.

“I walked into that room and saw what looked like a person strapped to a rocket ship going into outer space. He was literally yelling ‘Whoa!’ and his eyes were about the size of saucers,” says Halfpap. The patient’s blood pressure had gone from 80 systolic to 190 systolic in a couple seconds, he adds.

“Looking back, I should have been in the room. I could have potentially prevented that.”

**Value in Emergency Pharmacy**

Emergency departments (EDs) have become a primary-care destination for patients, and they are ordering more medications regularly. “Emergency departments are becoming much, much larger, and we’re providing a lot more care in them than we ever have before,” Halfpap says. Because of this change, it’s essential to have a pharmacist in the ED to consult on the appropriate care of patients, and for medication review and recommendations.

The response among physicians and nurses is typically favorable, as they tend to feel more at ease with a pharmacist present, he says.

“They feel more comfortable having a pharmacist in the emergency department because we’re there to answer a lot of their questions,” he says. “If you’re the physician, you can cognitively kind of offload a lot of the medication decisions because you know you can have the pharmacist [involved] in these more complicated, more complex decision-making processes.”

Halfpap has worked in the ED at University of Wisconsin Hospitals and Clinics, which has 24-hour pharmacist coverage, for 12 years.

Effective communication among team members is essential because members of the care team might be focusing on a variety of tasks at once or in different locations. For example, the attending physician might be calling in by phone from home, while the nurse might be managing multiple patients.

Brian Gilbert, PharmD, emergency medicine clinical specialist at Wesley Medical Center in Wichita, KS, works 10- or 11-hour shifts, seven days on and seven days off. In this role, he often responds to trauma incidents, stroke and sepsis alerts, and cardiac arrests. A key area where he uses his pharmacist training is in medication reconciliation,
in addition to providing counseling to patients, doctors, or nurses regarding drug information.

Still, Gilbert says that some doctors and nurses can be territorial, especially if they don’t have experience working with pharmacists. That’s why he advises pharmacists who are new to the ED or the trauma environment to refrain from “throwing themselves into the action.” It is better to introduce yourself to doctors, nurses, and patients, and tell them you’re there to help, he says. Or better yet, offer to do something specific, such as bringing a patient into a room.

Learning nurses’ priorities, by setting up a meeting with nursing leaders, is also very important, he says.

Part of the Action
Halfpap says ED pharmacists should make sure they’re in the emergency room, not in their offices. They need to approach the bedside as a member of the clinical team and strive to deliver value to doctors and nurses.

For example, pharmacists can offer medication-dosing recommendations, call the poison-control hotline about a patient incident, or offer alternatives to generally prescribed medications.

The latter is what Natalija Farrell, PharmD, pharmacy clinical specialist lead in emergency medicine at Boston Medical Center, did when a 30-year-old patient with sickle cell disease presented in the hospital’s emergency room with shortness of breath and in cardiac arrest.

When this patient presented, a bedside ultrasound suggested that she was experiencing a pulmonary embolism, and the clinical team began to discuss whether to use alteplase, a blood clot medication that’s not typically used in cardiac arrest situations.

“My role as a pharmacist was to determine the most appropriate dose for the patient, as well as to provide the nurse with information on how to administer it, and to make sure that the team’s resuscitation efforts were at least 15 minutes after alteplase was administered in order to make sure that the drug had time to work,” she says.

Farrell then prepared the medication, the nurse administered it, and the medication successfully broke up the blood clot in the patient’s lungs. At that point, Farrell helped the team determine the appropriate time to begin systemic coagulation therapy with heparin, in addition to the appropriate dose and cadence for monitoring.

Process Improvement
Pharmacists in the ED also can help improve processes, says Amber Meister, PharmD, critical care pharmacy manager at Wesley Medical Center. For example, they can create antibiotic order sets when ED clinicians need to treat a sepsis infection. This decreases the time clinicians need to think about the appropriate treatment, especially with sepsis infections when hundreds of medications are available, she says.

At Boston Medical Center, Farrell helped determine protocols for patients discharged from the ED with opioid prescriptions. She served on multidisciplinary committees in the ED and collaborated with the center’s addiction medicine leadership to create evidence-based guidelines for treating opioid withdrawal. The protocols include medication selection, dosing, frequency, monitoring, and adverse effects. Naloxone is stocked in the emergency room because of her efforts.

Farrell and other pharmacists help identify patients at risk of substance abuse through their practice of reviewing the medications patients have at home. Patients who are at risk for overdose receive take-home naloxone rescue kits.

Aine Cryts is medical writer based in Boston.
The number of independent pharmacies in the United States continues to slowly decline. In 2011 there were 23,106 independent pharmacies; by 2017 that number dipped to 21,909, according to NCPA Digest.

Chris Paddison, partner in the health practice at A.T. Kearney, a global management consulting firm, expects the number of independents to continue to decline. “Many large retailers are making attractive offers for independent owners to sell their businesses,” he says. “Many independent operators are older and looking for an exit, while younger pharmacists are less attracted to the risk and return of ownership.” He projects the number of independents to fall below 20,000 before 2025.

Tom Block, vice president and head of the global pharmacy practice at Dunnhumby, a customer data science platform, also predicts fewer independent pharmacies will exist in the future due to competition from drug chains, supermarkets, and mass merchants that have reached into many geographic areas that independents previously served. However, he doesn’t expect them to disappear.

In fact, he says many new independents will open and flourish. “We’re seeing a resurgence in independent operations as customers look for more unique offerings and services,” he says. Independent pharmacies still represent a significant portion of U.S. pharmacies, and no single pharmacy chain has more stores than all independents, which represented 35% of all retail pharmacies and a $77.6-billion marketplace in 2017, says B. Douglas Hoey, RPh, MBA, CEO of the NCPA.

Hoey is optimistic that independents will reap some success by implementing new policies, ideas, and business models focused on hands-on patient care, such as medication counseling and in-person delivery. “In many ways the market remains hungry for the kind of services independent community pharmacies provide that big box stores are not equipped for,” he says. “Community pharmacists don’t have to wade through corporate red tape or run things by a distant corporate office. They can make decisions that work for them and their patients.”

### Challenges Independents Face

A number of issues threaten independents:

- **High-touch care models and boutique offerings can differentiate stores and bolster business**

### Independent Pharmacies: Not Dead Yet

In recent years, many independent pharmacies have faced challenges from larger chains and mass merchants. However, they remain a significant presence in the U.S. pharmacy market, representing 35% of all retail pharmacies.

### Independent Pharmacist Salaries, 2018

<table>
<thead>
<tr>
<th>Salary Range</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>&lt;$100,000</td>
<td>13%</td>
</tr>
<tr>
<td>$100,000-$110,000</td>
<td>19%</td>
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<tr>
<td>&gt;$150,000</td>
<td>21%</td>
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#### Do you feel like you are adequately compensated?

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<thead>
<tr>
<th>Group</th>
<th>Yes</th>
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<tbody>
<tr>
<td>Independents</td>
<td>64%</td>
<td>36%</td>
</tr>
<tr>
<td>Total profession</td>
<td>59%</td>
<td>41%</td>
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Source: Drug Topics 2018 Salary and Job Satisfaction Study. Search “survey” on our website for more on pharmacists’ income, raises, professional satisfaction, and sentiments on industry trends.
Seven Survival Tips for Independents

Standing behind the counter and waiting for customers to walk into your pharmacy is not enough to sustain independents in today’s marketplace. Here are some new or unique things independents should consider to ensure survival, says B. Douglas Hoey, RPh, MBA, CEO of the NCPA.

Market unique services that your competition doesn’t offer.

Get on social media and promote special services and local events you're involved with. Network with your community contacts, who may have a need for your services. Talk to your peers and state pharmacy association about what marketing strategies have worked for others, Hoey says.

Offer a range of higher touch services and unique products.

Examples include clinical services, home delivery, medication management, and compounding. Become involved in nontraditional pharmacy businesses such as specialty drugs, or contract with the provider of prescriptions for long-term care facilities. “These business operations are quite different than operating a traditional pharmacy and might require additional accreditation or licensing, but they do garner more revenue streams,” says Tom Block, head of the global pharmacy practice at Dunnhumby.

Capitalize on niche opportunities.

Examples include immunization programs, medication synchronization, medication therapy management, disease state management, travel vaccines, nutrition depletion therapy, and homeopathic therapy, says Chris Cella, RPh, national vice president of RxOwnership, McKesson, which provides advice on buying and selling pharmacies.

Take advantage of your location.

For the 2,000 regional independents that might be the only pharmacy location for miles, work to strongly connect with local community healthcare providers to become an integral part of their network. For urban independents that are located next to a medical office building, market to those doctors and patients, says Chris Padddison, partner in the health practice at A.T. Kearney.

Adjust your business model to reflect healthcare changes.

“Because healthcare has shifted from a fee-for-service model to a pay-for-performance model, you should provide information on how your customers can stay healthy,” Cella says. For example, employ an expert on the topics of healthy eating, nutrition, supplements, vitamins, and immunization.

Join the 340B drug discount program.

“Thousands of federally qualified healthcare facilities are eligible to participate in the government’s 340B program, enabling them to stretch scarce resources, reach more eligible patients, and provide more comprehensive services that help consumers obtain medications that they otherwise might not be able to afford,” Hoey says.

“I have seen some of these facilities are located in medically underserved areas, where independent community pharmacies already play a critical role in healthcare.”

Optimize your current footprint.

With data science capabilities in customer segmentation, it is possible to determine what customers value and what they purchase most. Use this information to ascertain critical categories and optimal size allocations. “Review categories to determine if they are important to best customers or if space can be freed up for other items,” Block says.

Opportunities to Be Had

Despite challenges, independent pharmacies can increase revenue by using technology and customer analytic software to understand the value of each customer, what motivates them, and how to optimize relationships. These insights provide businesses such as pharmacies with the ability to make better decisions around cash pricing, product promotions, and assortment as well as improve medication adherence, Block says. They can be combined with customer engagement activities such as personalized marketing and communications that allow a business to communicate the most relevant messages and offers to each customer and create a differentiated experience.

“While every pharmacy owner would like to treat each customer with...
the same high level of attention, only so many resources are available,” Block says. “These insights can help drive decisions, such as whether to make a late-night delivery to a specific customer versus investing in late deliveries for everyone.”

Although the front of a store is typically a limited space in both product and productivity, independents can use technological insights on their most valuable customers to help turn precious but often underused real estate into an incremental and high margin sales generator, Block says. Some pharmacies have focused on boutique beauty and skincare offerings, while others have prioritized home medical equipment.

### Owning Two or Three Pharmacies

Despite the number of independents declining, owning more than one pharmacy is actually a growing trend. In the 2018 NCPA Digest, for the first time the number of stores per owner surpassed two. “Pharmacy owners can aggregate their buying power through committed purchasing, which enables them to lower their prices,” Hoey says. “Another reason is that established independents usually prefer not to sell out to a chain and instead keep their legacy alive by selling to another independent in or near their community.”

Todd Evers, RPh, owner and pharmacist at Evers Group of Pharmacies in Collinsville, IL, says certain overhead costs are required in running a business: accounts payable, accounts receivable, human resources, information technology, and marketing. “Having multiple locations helps to spread out the costs,” he says.  

Karen Appold is a medical writer in Lehigh Valley, PA.

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**CONTINUED FROM PAGE 24**

86% of independents say they are satisfied with their current job versus 71% of the total profession

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<thead>
<tr>
<th></th>
<th>Independents</th>
<th>Total profession</th>
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<tbody>
<tr>
<td>Are you able to give patients the information and tools they need to be healthier?</td>
<td>88% YES</td>
<td>71% YES</td>
</tr>
<tr>
<td></td>
<td>12% NO</td>
<td>29% NO</td>
</tr>
</tbody>
</table>

Source: Drug Topics 2018 Salary and Job Satisfaction Study. Search “survey” on our website for more on pharmacists’ income, raises, professional satisfaction, and sentiments on industry trends.

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The number of independent pharmacies is declining but at a slower rate than in recent years

Source: NCPA Digest 2008-2018, compiled by Drug Topics
The 10 Most Exciting Drugs in the 2019 Pipeline

While the development and approval of new therapies is never a sure thing, looking at the current drug pipeline is a useful way to peek into the future of healthcare.

What are the next blockbuster drugs going to be? Where will big expenses be coming from? What disease states are going to get the most attention?

Predicting the pipeline is not a perfect science, but we looked at what could be some exciting releases this year. Here are 10 of the most important expected drugs of 2019, in order of their expected Prescription Drug User Fee Act (PDUFA) date. One was approved at presstime.

Ravulizumab (Ultomiris)
Company: Alexion
Approved: 12/21/2018
Indication: Long-acting anti-C5 monoclonal antibody for treatment of paroxysmal nocturnal hemoglobinuria (PNH).

Why it’s exciting: PNH is a rare bone marrow failure disorder that usually begins in a person’s early 30s. It results in uncontrolled complement activation which causes hemolysis and other issues.

For patients with severe PNH, the only current treatment is eculizumab (Soliris), also made by Alexion. For patients who do not respond well to treatment, the only cure is a blood marrow transplant. Ravulizumab needs less frequent doses, every 8 weeks, than eculizumab, which is administered every 2 weeks.

Sacituzumab govitecan
Company: Immunomedics
PDUFA: 1/18/2019
Indication: Antibody drug conjugate for treatment of metastatic triple-negative breast cancer (mTNBC) with at least two prior therapies for metastatic disease.

Why it’s exciting: According to Arash Sadeghi, PharmD, clinical pharmacist of pipeline and drug surveillance at Optum, this would be the first treatment for mTNBC—which accounts for 10% to 20% of breast cancer cases. Jonathan R. Ptachcinski, PharmD, BCPS, BCOP, clinical pharmacist practitioner at the University of North Carolina Medical Center, says that data from clinical studies (one showed an objective response rate of 34% with a median duration of response of 7.6 months and progression-free survival of 5.5 months) holds promise for patients who progressed through multiple lines of treatment and may not be candidates for other therapies.

Siponimod
Company: Novartis
PDUFA: 3/2019

Why it’s exciting: The National Multiple Sclerosis Society estimates that around 1 million Americans have MS. Of these, 85% will have relapsing-remitting MS, and 80% of those people will develop SPMS. If the FDA approves siponimod, it would provide another treatment option as the condition progresses from the relapsing forms of MS. No other drug has been consistently able to slow disease progression with in patient with SPMS, but clinical trials have demonstrated some ability for siponimod to achieve those results. Sadeghi says this drug could generate between $1 and $3 billion in peak revenue.

Esketamine nasal spray
Company: Janssen
PDUFA: 3/4/2019
Indication: Nasal spray for treatment-resistant severe depression.

Why it’s exciting: About 9.5% of the population experiences depression during a given year. About half of patients with depression do not respond to one therapy, and up to 20% do not respond to multiple treatments.

Esketamine is touted as a fast-acting alternative to selective serotonin reuptake inhibitor and serotonin and norepinephrine reuptake inhibitors antidepressants. It could be the first new drug to treat depression in 30 years and could reach more than $2.3 billion in sales by 2024.

Zynquista (sotagliflozin)
Company: Sanofi
PDUFA: 3/22/2019
Indication: SGLT-1 and SGLT-2 inhibitor used in addition to insulin therapy to improve blood sugar control in adults with type 1 diabetes.

CONTINUED ON PAGE 28 >
Why it’s exciting: If sotagliflozin is approved, it would be the first oral treatment for type 1 diabetes on the market. The market for type 1 diabetes is a $5-billion market this year.

Joshua D. Miller, MD, MPH, assistant professor of endocrinology and metabolism at Stony Brook University in Stony Brook, New York, says while the potential market effects—and potential patient side effects—of this drug remain to be seen, the drug is “newsworthy because all we’ve had is insulin.”

Diabetologists have long used medications off-label to treat diabetes, he says, though they have never used an SGL-2 inhibitor. This drug could be a game changer—if its benefits outweigh potential problems (especially concerning diabetic ketoacidosis).

Sotagliflozin is also currently in phase 3 trials for type 2 diabetes, and could receive a PDUFA for that indication later this year.

Risankizumab

Company: Boehringer Ingelheim/AbbVie
PDUFA: 4/25/2019
Indication: An interleukin-23 inhibitor for treatment of patients with moderate to severe plaque psoriasis.

Why it’s exciting: The psoriasis market is huge—according to Pharma Intelligence, it’s projected to be a nearly $7.5 billion U.S. market this year. In its first year on the market, risankizumab could capture $12 million in sales and $31 million by 2020.

One reason for its predicted success is its efficacy. Efficacy is measured with a psoriasis area and severity index (PASI). Patients with PASI90 improved 90% or more during the treatment period. According to Sadeghi, 75% of patients achieved PASI90 with risankizumab, compared with 48% for Stelara (ustekinumab).

The drug is also currently in phase 3 trials for Crohn’s disease and ulcerative colitis.

NKTR-181

Company: Nektar
PDUFA: 5/28/2019
Indication: A selective mu-opioid agonist for pain relief.

Why it’s exciting: With the opioid crisis ongoing, it seems odd to bring another opioid into the market. But NKTR-181 promises to be an opioid with a lower risk of dependence. According to Nektar, this is because it does not produce the same high levels of euphoria present with other opioids.

It has a low permeability across the blood/brain barrier.

Unlike many other addiction resistant opioids—which are often merely different formulations of existing drugs with a tamper-evident mechanism added or a long-acting formulation—NKTR-181 is a new molecular entity, a first-in-class opioid.

AVXS-101

Company: Novartis
PDUFA: 6/18/2019
Indication: Gene therapy for the treatment of spinal muscular atrophy (SMA).

Why it’s exciting: SMA affects around 20,000 people in the United States. While there is currently a treatment for SMA (nusinersen, Spinraza), it is wildly expensive, with costs of $750,000 for the first year and $375,000 per year after that. According to Sadeghi, AVXS-101 would be a direct competitor to nusinersen at a lower price tag even though it would still be wildly expensive. Novartis announced that it believes AVXS-101 would be cost-effective with a $4 to $5 million price tag for a one-time treatment, which could be a record price for a drug.

Viaskin Peanut

Company: DBV Technologies
PDUFA: 6/22/2019
Indication: Immunotherapy for treatment of peanut hypersensitivity in children aged 4 to 11 years.

Why it’s exciting: Peanuts are one of the most common food allergies—a National Institute of Allergy and Infectious Diseases 2010 report lists the prevalence as 0.6% of Americans, or approximately 2 million people.

Currently, there is no definitive treatment for peanut allergy—the only actions available are keeping patients with allergies away from their allergens.

Evenity (romosozumab)

Company: Amgen and UCB
PDUFA: 7/12/2019
Indication: Monoclonal antibody that inhibits the protein sclerostin for treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Why it’s exciting: According to Sadeghi, there are 10 million with osteoporosis in the U.S. currently, with another 18 million people at risk. Those numbers add up to a large market for osteoporosis treatments. According to Pharma Intelligence, the osteoporosis market will be around $4.1 billion in five years, and Evenity could capture around $550 million of that.

Nicholas Hamm is editor of Managed Healthcare Executive, a sister publication to Drug Topics.
Seven Apps for Pharmacists

Pocket
Ever come across an interesting study, article, or Drug Topics feature that you didn’t have time to read? Most people handle this in three steps: Leave 20 tabs open in a browser, close those tabs, and then never find them again.

Pocket solves this problem by giving you a central location to store articles, videos, images, tweets, etc., so you can view it when you finally have a minute. It can’t guarantee you’ll actually read that stuff, but at least you won’t have the excuse of having lost it.

If you save something in Pocket, it’s available wherever you have Pocket installed. So, if you save article on your phone, but hate reading on a tiny screen, save it for when are on your computer. You can see anything you have in Pocket without an internet connection.

Merck Manual Professional
There’s nothing like having a world of knowledge at your fingertips.

The Merck Manual has long been the go-to source for medical knowledge, and now you can put it in your pocket—without having to lug around a 20-pound book. The app still contains thousands of articles updated regularly by hundreds of physicians and pharmacists, drug reference information, illustrations, and much more—all for free.

Not sure about a condition a patient’s dealing with? Can’t remember what a medication does? Just want to show off? Pull out your phone, use the Merck app, and keep your expert status!

RxShortages
This is one of those apps that does exactly what the name suggests, keeps track of which drugs are in short supply. It is relatively simple to use and provides important information in an easy one-stop location.

The app pulls information from both the FDA and ASHP shortage lists, helping you keep up with any medication shortages that could affect you and your patients. Designed by a pharmacist, this open-source app is free and provides a place to track shortage trends and get the most up-to-date data.

statDISPENSE
statDISPENSE is another app that could help you each day in the pharmacy. It’s a virtual padlock that provides software-controlled access to the “tackle-box” style emergency medicine kits that are stored in senior living or long-term care facilities.

These kits can be accessed by anyone, and typically there’s no way to track who accesses them or when, or if patients have received their medications.

To fix this, healthcare workers can use statDISPENSE to open the kits. This prevents unauthorized users from accessing medication and tracks who opens the box at what time. This eliminates the problem of manual documentation while still giving immediate access to emergency medications.

Headspace
Working in a pharmacy is stressful, so before you think about getting to all those articles you never got around to reading, why not try to relax a little first?

For relaxation, there’s no better place to start than with some guided meditations. Headspace is designed to walk you through the basics of mediation, giving you the tools to be more relaxed and stress-free.

Headspace claims that meditation can reduce stress and help you stay focused—two things pharmacists desperately need to do their jobs effectively and safely. Best of all, the app has a series of short, guided meditations designed for those with busy schedules.

FocusList
If you’re looking for more ways to stay focused—at work or at home—you may want to start paying attention to how you approach the tasks you’re doing. You can’t get more hours in a day, so why not be more productive with the hours you have?

FocusList is an app based on a time-management method invented in the 1980s. Essentially, it involves working on a single task for 25 minutes, then taking a short break, followed by another 25 minutes of work.

FocusList helps you track the tasks you want to get done, then focuses on those tasks when it’s time to complete them. It allows you to track your time and see data on what you did or didn’t accomplish in a day or week. This provides a better understanding of what’s taking up your time and how to be more efficient.

Strides
If you’re still looking to be better at using your time wisely, try out Strides, an app that can help you develop better habits by tracking everything you do.

Want to drink more water in a day? Set a goal for an amount that makes sense for you and tell the app what you’ve done. Want to sleep more? Track how many hours you’re getting. The app will help you plan your days and weeks to make sure you get everything done.

Nicholas Hamm is editor of Drug Topics’ sister publication, Managed Healthcare Executive.
Blockchain technology is creating more ways for healthcare to increase safety and efficiency by decentralizing data. Nearly half of healthcare companies report that they are developing blockchain solutions, according to a 2018 global blockchain survey by PricewaterhouseCoopers Health Research Institute.

Blockchain is defined as an open record of transactions, or a ledger, that can be managed by and distributed to several stakeholders instead of being maintained in one location. The stakeholders are a part of a network that can add data to the ledger, and transactions can be vetted by the network. As the network verifies and accepts transactions, a block of data is created. Several transactions are linked in a chain, with each block building upon the data of a previous block.

Because the integrity of the data is distributed across several blocks, data tampering is more difficult, and transactions are easier to trace. In healthcare, this allows for several stakeholders from different silos, including providers, payers and pharmacies, to have access to data.

As the industry grapples with increased fraud and waste as opioid abuse continues to rise, blockchain technology can add more security and accountability to the distribution process, says Carly Guenther, managing director of life sciences supply chain for Accenture.

“Many controlled substances are still prescribed using paper prescriptions, which will only be identified during the dispense/claim adjudication transaction phase,” Guenther says. “With blockchain, we could create a secure distributed ledger that allows witness identification to be recorded at the appropriate times.” Blockchain enables real-time access for authorized individuals to view controlled drugs transactions. Stakeholders could include law enforcement, researchers, clinicians, and payers, she adds. Accenture estimates roughly 30% of business costs are locked up in point-to-point messaging, she says.

“How blockchain can reduce waste, fraud in pharmacy”

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“How blockchain can reduce waste, fraud in pharmacy”

Blockchain Barriers

| Healthcare companies cite their top barriers to blockchain adoption in the next 3 to 5 years. |
| Lack of trust among potential users | 47% |
| Regulatory uncertainty | 39% |
| Ability to bring network together | 37% |
| Blockchain interoperability | 36% |
| Inability to scale | 33% |
| Cost | 31% |

Source: 2018 PricewaterhouseCoopers Global Blockchain Survey

Connecting Silos

Though the benefits of blockchain in pharmacy are numerous, the industry has to overcome hurdles before the technology can be deployed to its fullest potential, says Darryl Glover, PharmD, MBA, chief clinical officer at Gerson Lehrman Group. “The main silo is that the members of the supply chain, manufacturers, wholesalers and inpatient/outpatient pharmacies, have not historically worked constructively together and have a lack of trust in each other’s motives,” Glover says. “It is exactly this lack of trust that makes blockchain powerful. It can serve as a bridge to interconnect these parties and allow them to share information more readily as trust develops.”
Glover says deploying blockchain in a pharmaceutical supply chain requires stakeholder to have interoperable communication. “Blockchain serves as a bridge between and within the individual organizations to connect their systems together that do not readily communicate with each other. The data would definitely be more secure, and the network could be extended to include patients,” Glover says. “In this way, all of the members of the supply chain would be involved, and this then opens up possibilities for gaining access to data that was not previously possible.”

Using blockchain in the supply chain can also reduce the risk of fraudulent drugs infiltrating the supply chain. “Counterfeit pharmaceuticals are now considered to be the world’s largest fraud market. Blockchain technology could provide an answer,” Guenther says. “Packages have labels that are scanned at every point along its journey from factory to pharmacy. These labels would connect to a blockchain system.”

**Blockchain Solutions in Action**

A collaborative effort between Lipscomb University and a nonprofit pharmacy in Tennessee will use blockchain technology to provide drugs to customers who are underinsured. In November 2018, the university announced a collaboration using technology created by RemediChain that allows patients to donate their unused oral chemotherapy drugs to patients with financial difficulties.

Using blockchain, RemediChain is growing its network of prescription drugs that can be redistributed in an effort to eliminate waste in the industry. The company accepts prescription donations from patients across the country. When a donation is accepted, it receives a date, time, and location “stamp,” and is entered into the blockchain system. That medication is then tracked along every point in the chain of custody until it is either taken by a patient or properly destroyed.

RemediChain is already being used in a statewide, nonprofit pharmacy in Iowa, and Philip Baker, PharmD, CEO of RemediChain, says they plan to deploy the technology across nonprofit pharmacies across the country.

“RemediChain will allow us to tap into the vast amount of unused medicine that lies in the hands of patients and distribute those medications to our network of charity pharmacies all over the country,” Baker says.

**The Future of Blockchain**

In the next five years, more blockchain solutions connecting manufacturers and distributors to track chain of custody will be common place, Baker says.

“In 10 years, we’ll see pharmacies that run on their own cryptocurrency (or token), eliminating the need for pharmacy benefit managers and third-party payers,” Baker says.

However, Guenther says because specialty pharmacies and independent pharmacies are small, they probably will be the last dispensers to link up to any blockchain ledger because of the complexity and expense.

“Lack of specialty pharmacy participation will be a hurdle to success because last-mile delivery of the therapy to the patient is critical, and the cost of specialty drugs are material to payers,” Guenther says.

But even small and independent pharmacies can see the benefits are deploying blockchain in the immediate future, Glover says.

“Blockchain is the right tool if there is a need to create an interoperable network between systems that do not readily connect to each other or there is a need for business or regulatory reasons to have true data provenance,” Glover says. “The only investments that need to be made are in connecting the systems to the blockchain and creating a user interface. Blockchain technology itself is free to use and some time would need to be invested to create a private blockchain, or it could be outsourced.”

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**Blockchains: Where to Start**

Carly Guenther, managing director of life sciences supply chain for Accenture, says pharmacies should consider three things before planning to invest in blockchain technology:

1. **Identify the Use Case**

   Start with the business challenges that need to be addressed. There are plenty of use cases that do not make sense for blockchain, so nailing down the priority use cases that are relevant for blockchain is a critical first step.

2. **Plan and Design for Proof of Concept**

   This allows for experience to be gained on the power of the technology, appreciation of what is required for broader scale success, and the ecosystem/partners that need to participate.

3. **Stay Grounded on the Business Value**

   Investments in proof of concepts are generally fairly light, but they provide significant value in learning how to take an organization’s utilization of blockchain to the next level.

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**Donna Marbury is a healthcare, technology, and business journalist based in Columbus, OH.**
Duvelisib for Relapsed or Refractory CLL/SLL

The FDA has approved duvelisib (Copiktra, Verastem) for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.1 CLL and SLL are types of non-Hodgkin lymphoma.2 Duvelisib is an oral phosphatidylinositol 3-kinase (PI3K) inhibitor with dual activity against delta and gamma kinases, which are expressed in malignancies like CLL and SLL. Inhibition of PI3K reduces tumor cell proliferation, and decreases differentiation/migration of tumor support cells. Duvelisib also inhibits B-cell receptor signaling pathways, T cell migration, and macrophage polarization.3

Efficacy

Approval for CLL and SLL came from the clinical trial DUO; an open-label two-arm randomized phase 3 superiority trial designed to evaluate the efficacy and safety of duvelisib compared to ofatumumab in patients diagnosed with relapsed or refractory CLL/SLL.4 In the trial, 313 patients were randomly assigned to receive duvelisib 25 mg by mouth twice daily or intravenous ofatumumab at an initial dose of 300 mg, followed a week later by 2,000 mg once weekly for 7 doses, then 2,000 mg once every 4 weeks for 4 doses.1

Median progression-free survival was significantly longer in the duvelisib group—13.3 months versus 9.9 months (hazard ratio [HR] = 0.52, p<0.0001). The overall response rate for duvelisib was significantly higher than that of ofatumumab (73.8% versus 45.3%; p<0.0001). Median OS was not reached on either treatment arm with a 12-month probability of survival of 86% (HR = 0.99; 95% confidence interval: 0.65, 1.50).5

Side Effects

The most common hematologic adverse effects with duvelisib are neutropenia (33%), anemia (23%), and thrombocytopenia (15%). The most common nonhematologic adverse effects are diarrhea (51%), pyrexia (29%), nausea (37%), cough (21%), pneumonia (18%), constipation (17%), upper respiratory tract infection (16%), and vomiting (15%).6 Duvelisib has black-box warnings for dermatologic events, gastrointestinal toxicity, infection risk, and pulmonary toxicity. For dermatologic events with a severe cutaneous reaction, median time to onset was 3 months and typically lasted for 1 month. Stopping medication and giving supportive corticosteroids and/or antihistamines is advised.3

Diarrhea or colitis typically occurs in the first 8 months of therapy and monitoring should be done weekly for these side effects. Supportive management with antidiarrheals, corticosteroids, and treatment interruption, dose reduction, or discontinuation is advised.3

The most common serious infections were pneumonia, sepsis, and lower respiratory infections; most (75%) occur within 6 months. Treat preexisting infections before therapy initiation. If infections develop while on therapy, withholding duvelisib is recommended until infection resolves. Pneumocystis jirovecii pneumonia (PCP) and Cytomegalovirus have been reported; prophylaxis for both during therapy is suggested.3

If patients develop pulmonary toxicity, withholding treatment is advised until determination of infectious or non-infectious pneumonitis.1 Duvelisib is a part of the Risk Evaluation and Mitigation Strategy (REMS) program because of the black-box warnings. Providers receive a letter about the risks and are encouraged to give patients with a wallet care with safety information.6

Dosing and Cost

Recommended dosing of duvelisib is 25 mg orally twice daily, with or without food.7 If a dose is missed by fewer than 6 hours, administer it immediately. If the delay is more than 6 hours, administer the next dose at usual time. Pricing is expected to be more than $15,000 for sixty 25 mg capsules.3

REFERENCES

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1. Cut on the dotted line.
2. Rotate 180 degrees.

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New Year’s and a New Year

ew Year’s Day is just one of 365 days on the calendar, but I think most of us look forward to getting the previous year behind us and to begin anew.

My most memorable New Year’s Eve was 1980. At my instruction, Denise sat in her Dad’s rocking chair. I got down on one knee, opened a small box and asked “Denise Marie Kubitsky, will you marry me?”

The next day began 1981, the year we graduated pharmacy school, got married on July 4, and changed jobs a couple times. By November we had embarked on a 25-year career in independent community pharmacy, working for an eight-store chain near Altoona, PA. Never did I imagine the impact that Dec. 31, 1980, would have on most of my life.

On New Year’s Eve 1997, we made plans to join three families to ring in the New Year in a cabin at a local state park. We went to Headache Hill for an afternoon of sled riding. We loaded up our new toboggan and shoved off. We flew down the hill. Unfortunately we got a ditch, and everyone flew off the sled. My 10-year-old son landed on my left tibia and I heard a loud snap. I lay there in the snow, and they loaded all 300 pounds of me onto a pickup truck and hauled me down to an ambulance waiting on the road. I arrived at the hospital around 4 p.m. Dr. Charles Harvey, the orthopedic surgeon, came to the ER dressed in a tuxedo, ready for a wonderful evening. He looked at my X-ray and told the nurse, “Call my wife. I’ll be in surgery tonight.”

My hope for 2019 is that changes be made to this profession. It might be painful at first, but the long-term rewards will be of great benefit.

As a patient, I saw the difference compassion can make; the caring attitude of my orthopedic surgeon, nurses, physical therapists, occupational therapists and of course my family, got me through this most difficult year.

It also taught me a life lesson on how just a kind word, a pleasant smile, or making an enormous sacrifice as my orthopedic surgeon did, can make such a difference in a patient’s life.

There are a lot of resolutions that we make at the end of a calendar year. I promote this flip of the calendar to all my patients in the clinic as an opportunity to set a “quit date” to stop smoking. What better day to commit to a life-changing practice than to quit smoking?

Virtually every year my resolution is to lose weight. The average American gains at least six pounds over the holiday. What better way to end “eating season” than to commit oneself to a healthier lifestyle?

My hope for 2019 is that changes be made in this profession. Like a broken tibia, it might be painful at first, but the long-term rewards will be of great benefit. I’d like to see employers provide more staff and tools so we foot soldiers can do our job with a lot less stress. I’d like to see PBMs go away and reroute some of their extreme profits into the cash registers of the pharmacies that do all the work.

My biggest hope is for me and you to be able to enjoy this amazing profession, all along providing our patients with the care they so desperately need and deserve.
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