EXCLUSIVE SALARY STUDY

MONEY ISN’T ENOUGH

Why Strong Salaries, Raises and Bonuses Fail to Improve Professional Satisfaction

Arbitrary reimbursements | Inadequate support staff | Unreasonable expectations
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.
Tracking the Flu Season

The 2017-2018 flu season—one of most severe in recent U.S. history—drove home the need for increased vaccinations and for current data on the illness and its spread. Fortunately, the CDC, Walgreens, and other entities track the areas of the country where influenza is most severe and hospitalizations and mortalities attributed to the flu, and also provide updates on the effectiveness of anti-influenza drugs against the circulating influenza strains.

**Walgreens Flu Index**
Using weekly retail prescription data for antiviral flu drugs across Walgreens and Duane Reade stores nationwide, Walgreens Flu Index ranks the top 10 states as well as the top 10 designated market areas (DMAs) with flu activity by those experiencing the greatest gains in activity week-over-week.

“The Walgreens Flu Index can help pharmacists educate patients on the prevalence of flu activity in their communities, stressing the importance of getting the flu shot to help protect yourself and others from influenza,” Dorothy Loy, PharmD, director of immunizations at Walgreens, tells Drug Topics.

The data for the index, which was launched in December 2014, is analyzed at state and geographic market levels to measure absolute impact and incremental change of antiviral medications on a per store average basis, Loy says.

Walgreens updates the index each week during the flu season, with the turnaround time in data at just a few days, according to Loy.

**Weekly U.S. Influenza Surveillance Report**
The CDC’s Weekly U.S. Influenza Surveillance Report tracks influenza activity across all 50 states, and reveals the prevalence of flu strains by influenza A subtype (H1 or H3) and influenza B.

Especially helpful for pharmacists is the CDC’s antiviral resistance monitoring within the report. “All viruses tested since late May show susceptibility to the antiviral drugs oseltamivir [Tamiflu], zanamivir [Relenza], and peramivir [Rapibab],” CDC wrote in its November 24 report. Xofluza (baloxavir marboxil) will also be available this flu season.

Data for CDC’s weekly surveillance report comes from WHO and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories (which include both public health and clinical labs).

The labs, located in all 50 states, Puerto Rico, Guam, and the District of Columbia, report the total number of respiratory viruses detected by laboratory.

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**TOP 10 STATES WITH FLU ACTIVITY**
(2017-2018 SEASON OVERALL)
1. Texas
2. Oklahoma
3. Arkansas
4. Mississippi
5. Louisiana
6. Alabama
7. Tennessee
8. Kentucky
9. Nebraska
10. Kansas

Source: Walgreens

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**Estimated U.S. Influenza Disease Burden**, by Flu Season, 2010-2011 through 2017-2018

*Estimates from the 2015-2016, 2016-2017, and 2017-2018 seasons are preliminary and may change as data are finalized.

Source: CDC National Center for Immunization and Respiratory Diseases (NCIRD)
Influenza specimens tested for influenza and the number positive for influenza by virus type, CDC explains on its website. The Epidemiology and Prevention Branch in the Influenza Division at the CDC then collects and compiles the data and produces FluView, a weekly influenza surveillance report, and FluView Interactive, which allows for more in-depth exploration of influenza surveillance data—such as flu activity during past seasons.

The information allows CDC to track influenza-related illness, find out when and where flu activity is occurring, determine which viruses are circulating, detect changes in viruses, and measure the impact influenza is having on hospitalizations and deaths, Kristen Nordlund, a CDC spokesperson, tells Drug Topics.

There is a two-week lag time in the weekly influenza surveillance reports, Nordlund says. Influenza surveillance data collection is based on a reporting week that starts on Sunday and ends the following Saturday of each week. Participants summarize weekly data and submit it to CDC by Tuesday afternoon of the following week.

Other organizations and companies provide influenza prevalence reports. In partnership with the Weather Channel, U.S. Theraflu’s Cold and Flu Tracker aggregates social media mentions and community crowdsourcing to develop its “Sickscore,” an “easy-to-understand, real-time threat level of contagious cold and flu activity near you,” according to the web site.

Another influenza tracking resource is Flu Near You, created by Harvard, Boston Children’s Hospital, and the Skoll Global Threats Fund. Using crowd-sourced data from thousands of participants across the nation, the site lists flu activity for the past 7 days by state. Site visitors can also view the CDC’s weekly influenza data across the United States.

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**8 THINGS TO KNOW ABOUT THE SPANISH INFLUENZA PANDEMIC OF 1918–1919**

2018 marks the 100th anniversary of the Spanish Flu Pandemic, one of the worst pandemics in global history.

1. The global death toll for the Spanish flu is thought to be 50 million people, but it might have been as high as 100 million. In other words, between 3% and 5% of the world’s population died. In the United States, 675,000 people died. One third of the population became infected. The death rate in other influenza pandemics is usually around 0.1%.

2. During the Black Death Pandemic of the 1300s, plague (Yersinia pestis) killed 75 million to 200 million people, but the pandemic lasted longer than the Spanish flu, with the deaths spread out over more years. The death toll for the plague was also a greater percentage of the world population; it killed 30% to 60% of Europe’s population during the 1300s.

3. The Spanish flu was a more lethal form of flu virus, but it was not very different than other strains circulating at the time or since then. Almost all cases of influenza A except avian flu strains are caused by descendants of the Spanish Flu virus. Genomic sequencing conducted from autopsy samples and tissue samples from grave sites found that the Spanish flu was an H1N1 strain of flu. Some of the samples used for sequencing came from bodies buried in permafrost in Alaska.

4. The Spanish Flu is misnamed. It didn’t start in Spain. Nations that were fighting in World War I kept a tight lid on the news of the epidemic, but neutral Spain did not censor the news, which made people think it started there and spread.

5. In most influenza epidemics, the elderly, the infirmed and the very young make up the bulk of deaths. With the Spanish flu, many of those who died were healthy young adults. Some populations, notable Native American tribes, had very high death rates.

6. The pandemic occurred in three waves in 1918 and 1919, possibly starting in Austria in 1917. The first pandemic wave of influenza in the United States was in spring 1918, in several military camps. Troop movements at the end of World War I helped spread the disease. The waves that occurred in the fall of 1918 and winter of 1919 were deadlier than the first wave.

7. There had been influenza pandemics earlier, notably in 1889 and 1847. Later flu pandemics occurred in 1957 (Asian flu) and 1968 (Hong Kong flu).

8. The Spanish flu was so virulent that medical experts at the time were not sure if it was influenza. Some suspected the disease was a form of cholera or typhoid because of the high infection rate and severe symptoms.
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By Fredrick S. Mayer, RPh, MPH

Only a Healthcare Revolution Can Change Compensation Trends

I wish I could say I envision a bright tomorrow for pharmacist compensation. I want that, but these four things must happen first.

We Must Speak with One Voice
We must come together and speak with a unified voice on basic ideals such as public health, patient support, and the proper place of pharmacists as valued members of the healthcare team. And I am convinced we must gain the support of government to radically overhaul the profit-oriented system to one that is evidence based, that eliminates insurance companies, managed care organizations, and pharmacy benefit managers.

We need to change to a system that benefits the patient, such as a single-payer-type system like Kaiser.

We Must Emulate the European System
A review of how pharmacies are owned and operated in Europe reveals a much higher appreciation for the pharmacist’s role in healthcare. Some European countries regulate pharmacy and pharmacist density to ensure the appropriate number of professionals per capita for their citizens. Pharmacists are organized into a union or guild to negotiate with governments on reimbursement. Many of these countries, such as Denmark, Sweden, and Norway, ban chains and insist that the majority of pharmacies are owned and operated by pharmacists.

The Pharmaceutical Group of the European Union wanted to know whether weaker government regulation and the proliferation of chain pharmacies would result in better access to pharmaceutical care and lower drug prices. The study the group commissioned by the independent German firm OBIG examined practices in six European countries.

The European study found: “Assuming increasing competition and cost-containment as the two key aims of deregulation, the research undertaken in this study could not provide any evidence that these goals have been achieved through deregulation of community pharmacies.” On the contrary, it found that prices did not go down, competition did not increase, and service was less personal with chains.

We Must Strengthen the Pharmacist’s Role
The CDC has shown that in 2017, 42% of all flu vaccines were administered in pharmacy outlets in the United States, saving thousands of lives. This was accomplished by better reimbursement and increasing pharmacy profits as a result of state legislation under provider-status contracts instituted by more than 20 states. This needs to be done at the national level by Congress.

Unless regulation strengthens the pharmacist’s role, we will continue to have overworked, underpaid pharmacists and technicians forced to work under impossible circumstances, making grievous mistakes that result in injury and death. We will go right on being paid inadequate salaries to fill, count, pour, and type unreasonable numbers of prescriptions, with little or no opportunity to add life-saving value through counseling and consulting.

We Must Find New Leaders
We can only achieve a desperately needed regulatory support by advocating for it with a compelling, unified voice. My colleague Dan Hussar writes frequently about the need for pharmacists to unionize under the employee chain pharmacists’ banner, and to correct the oversupply of schools of pharmacy. Pharmacy professionals must organize with new leaderships, legislation, and regulation.

If we as a profession want to improve our own careers, and the health of our communities and our country, we had better focus forward and work toward these radical changes to save our profession. It’s time for a revolution.

Fredrick S. Mayer, RPh, MPH, is president of Pharmacists Planning Service and a member of the Drug Topics Editorial Advisory Board. He can be reached at ppsi@aol.com.
In 8179 statin-treated adults with well-controlled LDL-C (41-100 mg/dL) and CV risk factors including elevated TG (135-499 mg/dL) and either established CVD or diabetes and other CV risk factors¹,²

THINK FISH OIL DIETARY SUPPLEMENTS ARE THE SAME AS VASCEPA® (icosapent ethyl)?
THINK AGAIN.

Only VASCEPA has positive CV outcomes data¹

VASCEPA showed a 25% RRR in CV events¹* (HR=0.75 [95% CI, 0.68-0.83] \( P=0.0000001 \))

Fish oil dietary supplements are not intended nor proven to treat medical conditions

There is no generic equivalent or any other substitute for VASCEPA

RRR=relative risk reduction.
*Primary endpoint was a composite of first occurrence of CV Death, Nonfatal MI, Nonfatal Stroke, Coronary Revascularization, and Unstable Angina Requiring Hospitalization (5-point MACE).

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
- Significantly higher rate of hospitalization for atrial fibrillation or flutter, though rates were low (3.1% for VASCEPA vs 2.1% for placebo, \( P=0.004 \))

FDA-APPROVED INDICATION AND LIMITATIONS OF USE FOR VASCEPA³

- VASCEPA® (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients 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

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.


Please see Important Safety Information for VASCEPA on the following pages.
Please see Important Safety Information related to REDUCE-IT™ for VASCEPA on the following pages.
Please see accompanying Brief Summary of full Prescribing Information or go to www.vascepahcp.com.

<table>
<thead>
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FDA-APPROVED INDICATION AND LIMITATIONS OF USE FOR VASCEPA®

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- 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):

- 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 VASCEPA® (ICOSAPENT ETHYL) CAPSULES

IMPORTANT NEW INFORMATION: REDUCE-IT™ CARDIOVASCULAR OUTCOMES STUDY OF VASCEPA®

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 triglycerides [TG] ≥155 and <500 mg/dL).

- Patients were eligible to enter the trial if they were at least 45 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, hemoglobin 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 (86.6%), 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 6.4% 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 233.2 [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).

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Placebo N = 4090</th>
<th>VASCEPA N = 4089</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to first occurrence of cardiovascular death</td>
<td>903 (22.0)</td>
<td>705 (17.2)</td>
<td>0.75 (0.68 - 0.83)</td>
</tr>
<tr>
<td>Time to first occurrence of myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)</td>
<td>406 (14.8)</td>
<td>659 (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 (0.66 - 0.98)</td>
</tr>
<tr>
<td>Time to death by any cause</td>
<td>310 (7.4)</td>
<td>274 (6.7)</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 (6.1)</td>
<td>0.69 (0.58 - 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>216 (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>376 (9.2)</td>
<td>0.66 (0.58 - 0.74)</td>
</tr>
<tr>
<td>Time to first hospitalization for unstable angina</td>
<td>157 (3.8)</td>
<td>108 (2.6)</td>
<td>0.68 (0.53 - 0.87)</td>
</tr>
</tbody>
</table>

All presented 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 tertroary 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 MACE: 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 MACE: 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 predominately (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

[Graph showing Kaplan-Meier estimates for VASCEPA and placebo with hazard ratio, RRR, and NNT values provided]

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

[Graph showing estimated incidence with hazard ratio and comparison between VASCEPA and placebo]

<table>
<thead>
<tr>
<th>Patients with at Least One TEAE</th>
<th>N  = 4089</th>
<th>Placebo  N  = 4090</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VASCEPA</td>
<td>107 (2.6)</td>
<td>105 (2.6)</td>
<td>0.63</td>
</tr>
<tr>
<td>Placebo</td>
<td>106 (2.6)</td>
<td>105 (2.6)</td>
<td></td>
</tr>
</tbody>
</table>

Note: Treatment-emergent adverse events (TEAEs) are defined as events that first occur or worsen in severity on or after the date of dispensing 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 (N). Events that were positively adjudicated as clinical endpoints are not included.

Treatment-Emergent Adverse Events

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>VASCEPA  N = 4089</th>
<th>Placebo  N = 4090</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious TEAE</td>
<td>1252 (30.6)</td>
<td>1254 (30.7)</td>
<td>0.98</td>
</tr>
<tr>
<td>TEAE Leading to Withdrawal of Study Drug</td>
<td>321 (7.9)</td>
<td>335 (8.2)</td>
<td>0.60</td>
</tr>
<tr>
<td>Serious TEAE Leading to Withdrawal of Study Drug</td>
<td>88 (2.2)</td>
<td>88 (2.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Serious TEAE Leading to Death</td>
<td>94 (2.3)</td>
<td>102 (2.5)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Important Safety Information for VASCEPA from REDUCE-IT

- 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)
  - Constipation (5.4% VASCEPA patients versus 3.6% placebo patients)
  - Atrial fibrillation (5.3% VASCEPA patients versus 3.9% placebo patients)
  - 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=0.58)
  - 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% [-7.0 mg/dL] for VASCEPA and 10.2% [-2.0 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 some patients, this might have contributed to differences in outcomes between the groups. However, the relatively small differences in LDL-C levels between groups would not 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 assessment 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 more 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.

**POSSIBLE MECHANISMS OF ACTION**

Mechanisms responsible for the benefit shown in REDUCE-IT were not the focus of REDUCE-IT, but the banked 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).

VASCERA® (icosapent ethyl) Capsules, for oral use

Brief summary of Prescribing Information

Please see Full Prescribing Information for additional information about VASCERA®.

1 INDICATIONS AND USAGE

VASCERA® (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 VASCERA and should continue this diet and exercise regimen with VASCERA.

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.

2 DOSAGE AND ADMINISTRATION

Assess lipids 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 VASCERA, which should continue during treatment with VASCERA.

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

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

4 CONTRAINDICATIONS

VASCERA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCERA 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 VASCERA.

5.2 Fish Allergy

VASCERA contains fish esters of the omega-3 fatty acid, eicosapentaenoic 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 VASCERA. VASCERA 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. Rates observed in the clinical trials of a drug cannot be directly compared to rates in practice. 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 mutagenic 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 post-natal day 4 at human exposures based on a maximum dose of 4 g/day comparing body surface areas 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 VASCERA is administered to a nursing mother.

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 VASCERA, 33% were 65 years of age and over. No overall differences in safety or effectiveness were observed 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

VASCERA does not have any known drug abuse or withdrawal effects.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, 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. Hemangiomases and hemangiosarcomas 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 hemangiomases and hemangiosarcomas in all vascular tissues did not increase with treatment. In an 6-month carcinogenicity study in Tg.rasH2 transgenic mice oral with 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 VASCERA Full Package Insert for Patient Counseling Information

Distributed by:

Amarin Pharma Inc., Bedminster, NJ, USA

Manufactured for:

Amarin Pharmaceuticals Ireland Limited, Dublin, Ireland

Amarin Pharma Inc.

Bedminster, NJ 07921

www.VASCERA.com
CVS Pharmacy’s new CarePass loyalty program, which includes free prescription delivery, will likely help it better compete against Amazon and other online retailers, an analyst says.

“CVS and other retail pharmacies will want to boost their home-delivery capabilities so they are not playing catch-up with Amazon. Retail pharmacies feel an imperative to build their loyalty programs before Amazon applies greater focus in this field,” Ash Shehata, advisory principal for professional services firm KPMG’s Healthcare & Life Sciences Practice, tells Drug Topics.

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

“We are committed to designing and testing innovative programs that meet our customers’ health needs whenever, wherever, and however they want,” says Kevin Hourican, executive vice president of CVS Health and president of CVS Pharmacy, in a statement.

However, CVS faces stiff competition in the prescription-delivery arena since Amazon acquired the online drugstore PillPack, which delivers medications in presorted dose packaging and coordinates refills and renewals. Plus, other innovative online drug stores, such as Capsule Pharmacy, are competing for brick-and-mortar stores prescription business.

Shehata says CVS and other drug store chains can succeed in the prescription-delivery space. “CarePass doesn’t have the same benefits as Amazon Prime, but the program does offer value to consumers and expands upon its current loyalty program with the home-delivery benefit.”

Plus, CVS’s merger with Aetna adds numerous additional touch points to reach consumers, Shehata notes. The use of [CVS loyalty] data—paired with data from a PBM, an urgent care clinic, or the Aetna health plan—can help CVS obtain a 360-degree view of a person’s behavior and health situ-
We are a highly focused generic pharmaceutical company dedicated to delivering quality medicines to patients in need through excellence in innovation, development, manufacturing and commercialization.
Smalldoses

More Consumers Abandon Scripts Due to Cost

Nearly half of consumers have abandoned a medication prescribed by their physician because it was too expensive, according to a recent survey. The survey by DrFirst, an e-prescribing and patient medication management solutions firm, also found that 73% of consumers would change pharmacies if they knew that doing so would save them money on a prescription. As little as $10 in savings would motivate 38% of respondents to switch pharmacies. If the savings rose to between $11 and $25, nearly 70% of consumers would choose a different pharmacy, according to DrFirst. “Respondents’ willingness to change pharmacies to save money indicates that such advanced notice of prescription costs, coupon options, or lower-cost pharmacies would be highly valuable,” says the firm in a statement.

Only 44% of those surveyed said their physician advised them about medication costs or offered lower-cost therapeutic alternatives. “Even fewer (41%) reported receiving advice from their doctor or pharmacist about possible cost-saving coupons or having a prescription filled at a less-expensive pharmacy,” according to DrFirst.

However, retail pharmacists want to help patients achieve lower drug costs, B. Douglas Hoey, RPh, CEO of NCPA, tells Drug Topics. “Everyone agrees—some prescription drug prices are too high,” Hoey says. “And what other healthcare provider is both an expert on the effectiveness of medications and the cost of those medications than a community pharmacy owner?”

While recently enacted laws that prohibit gag clauses are a good step forward, there’s plenty more that can be done to increase patients’ ability to afford the medications they need, Hoey says. “As we keep working toward lower costs, we also strongly encourage patients to talk with their pharmacist,” he says. “Ask if the prescribed drug is the cheapest and most effective option for them. A community pharmacist would be happy to help.”

NCPA also continues to advocate for increased transparency, a streamlined prescription drug payment model, and a focus on the role played by “largely unregulated pharmacy benefit managers that contributes to the higher cost of prescription drugs,” Hoey adds.

Many Pharmacies Fail to Offer Naloxone

While pharmacies in many states are allowed to offer naloxone for opioid overdose reversal without a prescription, some do not have the medication in stock or are not offering it, new studies say.

Fewer than 25% of pharmacies surveyed in California said customers could pick up naloxone without a prescription, according to a recent study published in JAMA.

California pharmacies have been allowed to sell naloxone without a script since January 2016, but the study found that fewer than a quarter actually had the drug in stock.

In a related JAMA study, one in four pharmacies in Texas didn’t have naloxone available, even though dispensing it without a script has been legal there since September 2015.

However, 83.7% of pharmacies surveyed in Texas said they would dispense naloxone without a prescription.

“Improved training of pharmacists may be needed to make naloxone universally available for the prevention of opioid-related deaths,” writes Michael Steinman, MD, professor of medicine at the University of California, San Francisco, and Seth Landefeld, MD, chair of the Department of Medicine at the University of Alabama at Birmingham, in an accompanying JAMA editorial. “Such efforts will require resources, investment, and organizational support.”
Retail Clinics Boost Pharmacy Sales

In-store clinics are known to boost sales of over-the-counter medicines and other products in drug stores, but new data is revealing their true impact.

Sixty-eight percent of patients who used in-store clinics made a purchase in the store during the same trip, and 56.3% later made a subsequent visit to that store to purchase items, according to a study by Civis Analytics. The study involved two surveys of around 4,900 retail clinic users.

Difficulties making appointments with their primary care providers (25.2%) and lower prices (15.7%) were the top two reasons patients chose retail clinics. While cost is a major factor in choosing retail clinics, people with health insurance are equally likely to use them, according to Civis.

Many retail clinic patients were not regular customers (28.6%) or had never been to that store before (10.3%). Of first-time visitors 23.5% learned about the particular clinic they visited primarily by walking by, while 17.6% went there based on recommendations, and 11.8% saw or heard an advertisement.

The majority of retail clinic patients (90.3%) said their experience was good, very good, or excellent, and 81.7% said they would go back to a retail clinic in the future.

Civis also found that retail clinic users are more likely to have higher incomes than non-retail clinic customers, to be male, and to be healthy.

Community Pharmacies Collaborate to Curb Opioid Abuse

Several communities pharmacies, along with a pharmacy school and a substance abuse prevention organization, are working together to help solve the opioid abuse epidemic.

The new collaborative care model, Project Lifeline, seeks to improve public health through substance abuse screening and referral of at-risk patients in Blair County, PA. Funded by the NACDS Foundation, the project is led by the University of Pittsburgh School of Pharmacy’s Program Evaluation and Research Unit (PERU).

In addition to substance abuse screening, Project Lifeline aims to expand access to the opioid overdose reversal medication naloxone, build vaccination uptake for hepatitis B patients, and improve access to hepatitis C and HIV testing.

Project Lifeline uses an evidence-based approach to pharmacists’ delivery of early intervention for individuals at-risk for substance abuse: Screening, Brief Intervention, and Referral to Treatment. Blair Drug and Alcohol Partnerships provides a case manager who conducts assessments and referrals for substance use disorder to pharmacies.

“The consequences of the opioid epidemic have been far-reaching, and we are committed to evidence-based programs like this one that offer tailored, community-based approaches that hold the potential to impact patient care and communities broadly,” NACDS Foundation President Kathleen Jaeger said in a statement.

Naloxone Safe Past Expiration Date

Extending the shelf life of naloxone nasal spray (Narcan) and naloxone injection (Evzio) could greatly increase access to both forms of the opioid overdose-reversal medication, a study says.

The research was presented at the 2018 American Association of Pharmaceutical Scientists (AAPS) PharmSci 360 Annual Meeting in Washington, DC, in early November.

Researchers found that Narcan was chemically stable for at least 10 months past its expiration date, and Evzio was stable for more than one year past the expiration date. The shelf life of the medications range from 18 months to 2 years.

“The country is experiencing an opioid epidemic and, given the continued increase in opioid overdoses, our preliminary data suggests that extending the shelf life of these products should aid in avoiding the significant expense of replacing them every two years and also increase the availability of this life-saving medication in both stockpiles and communities,” says Charles Babcock, PharmD, the study’s principal investigator and an assistant professor at Marshall University School of Pharmacy, in a statement.

Naloxone’s short half-life may result in healthcare and community providers carrying or storing outdated product, adds Mohammad Faisal Hossain, MPH, PhD, instructor of pharmaceutical science at Appalachian College of Pharmacy. “What makes our research unique is that the products tested were unused, expired doses from these local providers,” he says in a statement.

In related news, FDA is making progress on advancing the development of an over-the-counter (OTC) naloxone product as a way to promote wider access for overdose treatments, says FDA Commissioner Scott Gottlieb, MD, in a recent statement.

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Civis also found that retail clinic users are more likely to have higher incomes than non-retail clinic customers, to be male, and to be healthy.
Better care at lower costs is the ultimate goal across healthcare today. As accountable care organizations (ACOs) become more common, healthcare organizations are working harder than ever to find cost-effective ways to optimize medication use. Pharmacists can help. Pharmacists are positioned to help develop data-driven cost savings plans and quality initiatives, and experts shared how this can be accomplished in “Optimizing medication use in value-based models of care: Insight into developing a successful collaboration between a health system and managed care organization,” a session presented in October at the Academy of Managed Care Pharmacy (AMCP) Nexus 2018 in Orlando.

Presenters Christopher Diehl, PharmD, MBA, BCACP, a clinical pharmacist for Excellus BlueCross BlueShield, and Erica Lynn Dobson, PharmD, manager of pharmacy services for Accountable Health Partners, highlighted how ACOs can use data to identify medications for targeted interventions, and how pharmacists can influence changes across clinically integrated networks. Diehl and Dobson described how collaborations between clinically integrated networks and managed care pharmacists work, and how these relationships could be developed further.

Diehl shared some insights from the presentation in a Q&A session with Drug Topics’ sister publication Managed Healthcare Executive (MHE).

MHE: What are your goals and takeaways from your presentation?

Diehl: The goals of this session are to share our methods of collaboration with an ACO to achieve our mutual goals of improving quality and reducing costs for consumers and employer groups who purchase health coverage. We presented in such a way so as to show both the health plan’s view and the ACO’s view of where we were able to align our goals, overcome barriers, and achieve strong results. Our primary message is that these collaborations must be a true partnership in which both sides are willing to compromise. Our results prove that it can work effectively, but it must be through teamwork, and not simply a one-way relationship.

MHE: What are some specific examples of how these initiatives can reduce cost and improve quality?

Diehl: We focused on our efforts with Glumetza [metformin], a drug used for diabetes that had a drastic price increase, as well as our efforts in choosing low-cost inhalers. Also, we discussed our attempts at improving quality by focusing on efforts with the new transitions of care medication reconciliation measure.

MHE: How can the management of high-cost medications and biosimilars improve health outcomes while also reducing cost? While biosimilars are replacing some higher-cost biologics, this has not caught on as fast as it has overseas.

Diehl: Biosimilars are difficult because there are still some unknowns in terms of regulation and evaluation. While biosimilars are coming in at a lower cost, physicians have been somewhat hesitant to begin prescribing them. Using our relationship with the ACOs, we were able to provide information and allow the ACOs to work with their own physicians in ways that can be more effective than traditional managed care methods. We continue to educate and promote biosimilars when feasible, but also have another avenue of communication when needed.

MHE: How can outcomes and costs be improved?

Diehl: We hope that our session will lead the attendees to have more effective relationships with their ACOs. By highlighting opportunities and describing the barriers and challenges to our success, we can help provide attendees with strategies and solutions to overcome those barriers and improve their relationships.

Rachael Zimlich, RN, is a writer based in Columbia Station, OH.
Specialty pharmaceuticals make up a significant part of the current drug market, and their impact is only going to grow over the next few years.

That’s according to an analysis of the specialty market and pipeline by Aimee Tharaldson, PharmD, senior clinical consultant of emerging therapeutics at Express Scripts, who spoke about specialty pharmaceuticals in development at the AMCP Nexus meeting in Orlando in October.

The specialty market made up 41% of the total drug spend in 2017. That number, Tharaldson said, is likely to increase. There will be a fifty-fifty split between specialty and traditional medications in the coming years, she said.

In total, the 2017 per-member per-year specialty spend was $444. Of that amount, the largest contributor was anti-inflammatory medications ($157), followed by oncology ($70), multiple sclerosis ($60), HIV ($45), and Hep C ($19).

Here are five things you should know about the specialty pharma pipeline:

1. The number of newly approved drugs is increasing every year.

The future of specialty medications, according to Tharaldson, will be defined by increased competition and a variety of high-impact indications.

2. The biggest competition factor will be biosimilar approvals

Through 2022, there will be a $54.4-billion potential for biosimilars as 71 specialty drug patents will expire, Tharaldson said. Biosimilars could provide “significant” cost savings, but they are not without their problems, she said. Biosimilars face a variety of legal hurdles and will also struggle to gain market share.

3. The top two pipeline categories are cancer and orphan drugs

Tharaldson also covered several important categories that will be largely influenced by specialty medications in the coming years. The two biggest pipeline categories are oncology and orphan drugs, but other smaller indications could still play a significant role, she said.

Orphan drugs make up the largest slice of the specialty pipeline at 45%, with cancer drugs the second-largest class at 20%. According to Tharaldson, 30% of new orphan drugs will be blockbuster drugs.

4. NASH could see major drug developments in 2019.

One other notable treatment class is for nonalcoholic steatohepatitis (NASH). Currently, NASH has no treatment. But according to Tharaldson’s data, there are 10 medications in the pipeline, and one could be approved as early as the end of 2019. Some analysts expect this could be as much as a $35-billion-per-year industry, though Tharaldson said that number could be too high.

5. The Alzheimer’s pipeline is promising

In the even longer term, Tharaldson pointed out that the Alzheimer’s pipeline may be productive. Current treatments for Alzheimer’s are only symptom modifying, whereas new drugs could finally be disease modifying agents.

While these drugs—if they are even approved—won’t be available for years, they could significantly alter the Alzheimer’s treatment landscape.
Reimbursement and Other Challenges in 2019

December and January are the time of year to look both ways, backward and forward. In this issue, we looked back at how well the profession has been treating its members. But we also took the opportunity to ask a handful of pharmacy professionals what challenges they think pharmacy will face in 2019.

Here are their answers.

Jerry Callahan, RPh, owner of several Medicine Shoppe Pharmacies in Missouri:
The No. 1 challenge for pharmacists in 2019 can be reduced to one word: reimbursement. The low, and oftentimes below-cost, reimbursements, and the ever-expanding DIR fees are the biggest challenges facing pharmacy, in particular the independents. At times, independent pharmacies are being paid less than the chain pharmacies even though we often do more for the patient then the chains do.

Van G. Coble, DPh, Winfield, KS:
While I retired earlier this year, reimbursement from PBMs has been an ongoing problem. Before I retired I was back to seeing virtually every prescription filled via the checking process, and there sure seemed to be more reimbursements under the cost of the drug, and a large number where the gross profit was less than the cost to dispense.

Secondly, PBMs have infiltrated every portion of the process of prescribing and dispensing medications, along with holding hostage manufacturers, pharmacy services administration organizations (PSAOs), and even wholesalers who have PSAOs. PBMs serve a purpose: rapid processing and adjudication of claims for prescriptions. But they make money the old fashioned way: by stealing it. Unless one works and pays attention to reimbursements on a daily basis, this might not be apparent. The continual merger of PBMs with pharmacy chains and/or health insurance companies will only continue to worsen the situation.

Mohamed Jalloh, PharmD, assistant professor, Clinical Sciences Department, Touro University California College of Pharmacy:
I think the key challenges pharmacists will face in 2019 are:

- A shortage of community pharmacy positions due to greater automation and greater number of mail-order pharmacies (like Amazon’s Pill Pack).
- A greater need of clinical training for community pharmacists since big chain pharmacies will pursue revenue generation using pharmacist-centered models (naloxone dispensing, oral contraceptive dispensing, etc.).
- An increase in the need of ambulatory care pharmacists as primary care physician quality of life continues to decline.
- A higher number of positions requiring residencies while fewer residencies are being created.

Pete Kreckel, BSPharm, pharmacist at an independent pharmacy in Altoona, PA:
One big challenge is having enough staff in the pharmacy to do the job well, and to help our patients who need our expertise. Valuable pharmacist time is tied up putting away orders, answering phones, and other mundane tasks that could be completed by staff, if we had enough staff.

Another challenge, especially for independent pharmacies, is being excluded from networks. How can our government take independent pharmacy tax dollars and channel those funds to the chain pharmacies by excluding us from the preferred networks? We independent pharmacies are buying the rope that is being used to hang us with.

Bruce Kneeland, a community pharmacy consultant:
The biggest obstacle pharmacy faces is realizing that reimbursement for dispensing services is not going to improve—and that is okay. Many new, appropriate, and profitable healthcare services are emerging. For example, pharmacies are selling products that help with drug nutrient depletion, providing weight-loss programs, operating travel clinics that go way beyond immunizations, and helping family caregivers with medication packaging services. People are willing to pay out-of-pocket for a myriad of healthcare services.

Another major obstacle pharmacy faces is the lack of faith so many pharmacists have in their ability to provide, and charge out of pocket for, healthcare services. I believe “owning” dispensing is a critical aspect of the profession. But, I also believe coupling dispensing with other services is critical to the future success of the profession. Many healthcare providers make an excellent living by providing services for which insurance companies do not reimburse.
Job got you down? As pharmacists continue to battle professional challenges that include low payments, hidden fees, higher volumes, insufficient support, and a healthcare system that relegates them to a service department, it appears as though no amount of money could offset systemic frustrations. Pharmacist compensation continues to rise, but modest financial increases aren’t making pharmacists any more satisfied in their jobs, according to the annual Drug Topics Salary and Job Satisfaction Study (see Methodology, p. 17). For the third year in a row, pharmacists report higher workloads, more stress, and less overall job satisfaction despite individual incomes that are twice the national average than those of entire households.

More than 70% of pharmacists earn at least $120,000 per year with significant bonuses and benefits, yet more than a quarter of pharmacists are dissatisfied in their current position, and 41% say they are not adequately compensated for the work they do. The reasons for their disillusion are primarily caused by the mix of workload expectations, insufficient support, and variable reimbursements that many consider arbitrary.

Compensation
Half of pharmacists are paid salaries while half work on an hourly basis. In 2016, 57% of pharmacists were salaried employees; 52% were salaried last...
year, and this year’s even split continues the trend toward hourly employment. More than two-thirds of respondents work between 30 hours and 44 hours per week; 12% work fewer than 30 hours, and 19% work at least 45 hours per week. Few (2%) reported working more than 60 hours per week.

Salaries remained strong in 2018: 71% of respondents made more than $120,000 this year, on par with last year but up significantly from 2016, when just 61% made at least $120,000. Another positive trend: 18% of respondents made more than $150,000 this year, up from 15% last year and up from 7% in 2016 (Chart 1, p. 18). The more salaries at the top of the range show that despite the glut of graduating pharmacists, there is still room at the top for those with management experience and those willing to work in high-volume locations in big cities.

Hospital pharmacists tend to make more money: 82% of hospital workers make more than $120,000 per year; 25% make at least $150,000, and just 5% make less than $100,000 per year compared to 10% of all pharmacists who make less than $100,000. Similarly, managed care pharmacists and those who work in nursing home/long-term care pharmacy are more likely to earn salaries (66%) versus an hourly wage, and 32% earn more than $150,000 per year, making health system pharmacists almost twice as likely to earn salaries in the top range for the profession. Not surprisingly, health system pharmacists are more likely to receive regular raises (68%) but less likely to receive bonuses or additional incentives; 70% of health system pharmacists say they are adequately compensated for what they do, and just 15% say they are dissatisfied in their work compared to 27% of all pharmacists.

Does higher education mean more money? The short answer is yes, but there appears to be a point of diminishing returns. The Drug Topics Annual Pharmacist Salary and Job Satisfaction survey was emailed to our newsletter audience on Sept. 13 and Sept. 20. The survey was in the field for 13 days and received 1,230 responses, which gives the survey a ±2.75% margin of error with a 95% confidence interval or a ±3.6% margin with a 99% confidence interval.

For the first time, the gender of respondents was evenly split, and age is more or less evenly distributed: 20% are under 40 years old; 22% are age 40 to 49; 25% are 50 to 59, and 32% are 60 or older. More than half of respondents have 25+ years of experience. Just 8% of respondents have earned master’s degrees; 41% have earned PharmDs, and 14% are board certified. Almost half of respondents work in a retail setting, and 82% of respondents are employed full-time; 10% are employed part time, and 8% are independent consultants, contract employees, retired pharmacists, or unemployed. The mean number of pharmacists per location was 15, and the median number of pharmacists per location is 4. The charts below show the breakout of respondents by geography, title, and type of pharmacy.
return. Only 14% of those who are board certified say their certification helped them draw a higher salary; 10% are unsure, and more than 75% say it has no impact on salary. The data (Chart 1) confirms that sentiment: 74% of board-certified pharmacists make more than $120,000 per year, just a tick above overall respondents. They are no more likely to say they are adequately compensated, satisfied with their current positions, and receive regular raises or bonuses.

**Wages, Raises, and Bonuses**

Wages (Chart 2) generally correlate to salary. Health-system pharmacists earn more per hour than community pharmacists, and education level has a marginal effect on earnings. One troubling trend is a decline in regular raises: 47% of all respondents received a raise in 2018, down from 53% last year and 62% in 2016. For those who received raises, the lion’s share were 3% or less, similar to years past (Chart 3).

Additionally, the number of pharmacists receiving bonuses, incentive pay, or other profit-sharing rewards continues to decline. In 2016, 55% of pharmacists received a bonus; that number fell to 43% last year and 42% in 2018. Two-thirds of those who received additional bonuses say those earnings were $5,000 or less; 15% earned between $5,000 and $10,000, and 15% received bonuses of $15,000 or more, up from 7% in 2016.

Men tend to receive larger bonuses than women, although this could be attributed to tenure, as 60% of men have at least 25 years of experience versus 45% of women. While men and women received bonuses at a similar rate, 44% and 40% respectively, men (20%) were more than twice as likely to receive a bonus of at least $15,000 versus women (9%); 57% of men received bonuses of less than $5,000, whereas 73% of women who earned bonuses received less than $5,000.

**Satisfaction**

Job satisfaction metrics haven’t changed significantly in the past few
years, which means they still aren’t good (Chart 4): 27% of respondents say that are dissatisfied in their work in some way, and almost one-third of respondents (29%) say that are considering a job change in the next 12 months, up slightly from 27% from last year and on par with 2016 numbers.

Two-thirds of respondents say they have more stress compared to last year, up from 60% in 2017 who said their stress had increased. Similarly, 72% said workload increased versus last year’s workloads, and just 4% say their stress and workload had decreased, although many who reported less work and stress had voluntarily reduced their responsibilities, for reasons like their run up to retirement.

The reasons why job stress is on the rise and job satisfaction is low is fairly predictable: Increased workload volume and inadequate support staff reign as the largest frustrations (Chart 5). With increased responsibilities for MTM, vaccinations, and patient-care services that are migrating to pharmacies, there is a critical need for better-paid and better-educated technicians, but this isn’t happening in the current environment driven by employee-per-volume metrics.

Paperwork, EMRs, and practice management software aren’t making work easier, either: 45% say documentation is a cause of stress, much of it a result of antiquated management/patient systems or inadequate training on new systems.

The DIR system, hidden fees, coercive negotiating practices by PBMs, and audits continue to be major frustrations for community pharmacists who own and/or manage purchasing

**Why has your stress level at work increased?**

- Increased work volume: 78%
- Inadequate staff support: 70%
- Increased paperwork: 45%
- Negative workplace environment: 38%
- Other: 17%
- Lack of training and education: 15%

**Why has stress increased?**

- “Lack of respect and appreciation by supervisor, doctors, and patients.”
- “Corrupt and abusive practices of the PBM industry: below-cost reimbursement, DIR fees, PNR fees, rebates, deceptive practices, and audits that invent rules as they go along.”
- “Opioid crisis has increased our workload; it’s a nightmare for pharmacy staff.”
- “Negative reimbursement, increased legal risk.”
- “PBMs are killing us.”
for their outlet, driving many to look for greener pastures elsewhere. It’s unclear the extent to which the current healthcare system contributes to general sentiments about income (or revenue), job satisfaction, and poor workplace environment, which is also a major factor driving pharmacists to find new jobs. Professional advancement, job security, and income were cited by more than 1 in 4 as reasons for looking for new work (Chart 6).

Administering vaccinations is a growing reality for pharmacists, but the brunt of vaccinations happen at community chain pharmacies. Not surprisingly, 75% of chain pharmacists say they must deal with unrealistic vaccination quotas compared to one-third of overall respondents and other community pharmacists; 59% of chain pharmacists say it takes up too much of their time compared to 29% of all pharmacists and 33% of other community pharmacists. There isn’t much wondering why: 45% of all pharmacists do not administer any flu shots, whereas just 4% chain pharmacists skip the duty. One in three chain pharmacists administer more than 50 flu vaccines each week during peak season compared to 13% of all pharmacists and 12% of other community pharmacists (Chart 7).

The burden of vaccinations, corporate politics, workflow metrics, and the lack of time to give patients the information they need lead chain pharmacists to be the most disenfranchised sector of the profession. More than half (53%) of chain pharmacists say they are dissatisfied with their jobs, almost twice the proportion of the overall profession.

How does all this translate to the duty pharmacists have to their patients? In short, 71% say they are able to give patients the information and tools they need to be healthier; 17% are neutral, and 12% say they cannot give these services. For chain pharmacists, the workload toll is a concern for patient health. Double the number of chain pharmacists (24%) say they are unable to make patients healthier versus 58% that say they are able to deliver health information and tools.

David Frabotta is executive editor of Drug Topics. Send him your feedback, ideas, or letters to the editor at david.frabotta@ubm.com.

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**Chart 6: What are your reasons for considering a job change?** (select all that apply)

- Dissatisfied with current job 59%
- Professional advancement 29%
- Job security 28%
- Other 28%
- Income 26%
- Geographic location 17%

**Chart 7: During flu season, how many flu vaccines do you give in a typical week?**

<table>
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<th>Range</th>
<th>Percentage</th>
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<tbody>
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<td>18%</td>
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<tr>
<td>51-100</td>
<td>9%</td>
</tr>
<tr>
<td>More than 100</td>
<td>5%</td>
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</tbody>
</table>

**What changes need to happen at your pharmacy?**

- “More utilization of auto-dispensing cabinets.”
- “We are in desperate need of a union.”
- “Realistic support staff and hours, fewer reports.”
- “Some coworkers need to prioritize workload. I’m looking at you, Carol!”
- “Better trained and better paid technicians will reduce turnover and help pharmacists do more.”
- “Fewer restrictions on compounding; fewer roadblocks for prescribers.”

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**Reasons for considering a job change**

“Company is focused on metrics and not real patient care.”

“Too much extra work, like MTM, vaccines, med-synchronization.”

“Lack of staff, shifts are too long.”

“Metrics, lack of support staff, impossible workload.”

“Tired of wasting my life for someone else’s giant profit.”
More than 900 public and private accountable care organizations (ACOs) in the United States manage the healthcare costs of around 32 million Americans, according to healthcare consultancy Leavitt Partners. As that number grows, so does the number of pharmacists these organizations employ to optimize medication use.

ACOs are a reimbursement model where healthcare organizations strive to meet cost and quality targets. If successful, they receive higher reimbursement.

“While underutilized in early ACO models, pharmacists today are playing an increasingly important role in the success of these organizations, and more and more pharmacists are being hired on staff to oversee medication management and optimization,” says Susan A. Cantrell, RPh, CAE, CEO of the Academy of Managed Care Pharmacy (AMCP).

Half of all Americans take at least one prescription drug per-month, whereas almost a quarter take at least three prescription drugs per-month, according to the CDC. Without managing medication costs, which are expected to rise faster than any other medical expenses, ACOs will find it increasingly difficult to deliver cost-effective quality healthcare.

According to a recent study in the ACMP’s Journal of Managed Care and Specialty Pharmacy, ACOs that employ or contract pharmacists are better at managing medication costs while delivering value.

“That’s because pharmacists are uniquely positioned to help optimize appropriate medication use, reduce medication-related problems, and improve health outcomes,” Cantrell says. “As a clinical expert working as part of an interdisciplinary team, pharmacists can assess whether medication use is contributing to unwanted effects and can help achieve desired outcomes from medication use.”

Pharmacists in ACOs

A key aspect of a pharmacist’s work in an ACO is counseling patients. Pharmacists counsel them in drug therapy management clinics, such as anticoagulation clinics; transplant programs; and HIV, hepatitis C, psychiatric and lipid management clinics, to ensure that patients take their medications correctly and that drug-related problems are identified and managed.

They also play a key role in transitional care: counseling post-discharge patients on the proper use of any medications prescribed during their hospital stay. Not taking medications properly and/or not recognizing a side effect or symptom can land the newly discharged patient back in the hospital.

“ACOs currently working with pharmacists have seen positive results in reducing hospital readmission and ER utilization, particularly when they integrate pharmacists in their transitions of care teams,” says Stephanie Gernant, PharmD, MS, assistant professor at the University of Connecticut School of Pharmacy in Storrs.

“I think we’re going to see a greater surge of pharmacist integration in outpatient and primary care settings in the upcoming years. No matter your political ideology, payment based on value is never going away—the cat is out of the bag,” she says.

Currently, the percentage of ACOs working with pharmacists is 63% and that is likely to grow, says Gernant.
"An ounce of prevention is worth a pound of cure, and ACOs working with pharmacists—especially in primary care, preventative care, and risk management settings—see the return. For every adverse drug reaction a pharmacist discovers, for every omission of care she/he corrects, there’s a downstream positive patient outcome, and for ACOs that means dollars."

Pharmacists can help identify gaps in medication use or red flags that may not be as readily apparent to other providers, says Cantrell. “A pharmacist engaged in therapeutic drug monitoring knows if a patient is not filling a prescription or is taking multiple medications that have been prescribed by different doctors.”

Pharmacists can offer solutions to some of the challenges that patients face in taking medication. They can inform patients about what to expect during treatment, what side effects are common, or how long it might take for a medication to work. They can also help with the challenge of prohibitive costs by suggesting less costly generic alternatives.

**Pharmacists Expand Skills**

Interdisciplinary care in ACOs is growing because not only are today’s healthcare professionals being trained this way, but government organizations like the Agency for Healthcare Research and Quality (AHRQ) is investing in tools that maximize the role of each team member, like its TeamSTEPPS, says Ger- nant. This program is a teamwork system developed jointly by the Department of Defense and AHRQ to improve institutional collaboration and communication relating to patient safety.

College pharmacy courses are also providing skills that enable ACOs to make the most of future pharmacists as team members. “Students within the PharmD curriculum are introduced to managing costs throughout their coursework, both while in class and on experiential rotations,” says Alexandra Watson, PharmD, BCACP, assistant professor at Albany College of Pharmacy and Health Sciences. “Students are required to take Pharmacy Administration and Pharmacoeconomics during their professional coursework.” They learn about the healthcare system as well as techniques to assess economic outcomes, including cost-benefit analysis and cost minimization. In other courses, they have opportunities to apply cost management within real world scenarios and discuss ethical questions surrounding access to medication.

Students are given patient cases in which pharmacoeconomic barriers are addressed and resources including lower cost alternatives, coupons, or patient assistance programs are reviewed. They also conduct mock pharmacy and therapeutic meetings to reduce costs through appropriate de-prescribing or determining lower cost alternative therapies.

Training in pharmacology, pharmacokinetics, and pharmacoeconomics enables pharmacists to assess medication use in ways other healthcare practitioners might not be prepared to. “Since healthcare is moving away from fee-for-service and toward value-based care payment structures, pharmacists now have opportunities to further assist the team by helping meet quality markers,” says Watson.

**Specialty Pharmacy Fuels Momentum**

One reason pharmacists will play a larger future role in ACOs is the growing number of specialty pharmacy products on the market—medications that are often prohibitively expensive, need special administration, or require extensive monitoring to manage side effects.

“Patterns of care are shifting specifically to focus more on overall drug management due to more specialty pharmaceutical products becoming available in the market,” says Jane Lutz, executive director of the Pharmacy Benefit Management Institute (PBMI). “As a result, the clinical expertise of a pharmacist becomes more and more critical.”

Pharmacists can assist in managing costs in all settings, from managing formularies in the hospital to creating criteria for the use of new biologic agents in managed care, says Watson.

“Community pharmacists are often on the front line and can offer opportunities for interchange or decrease barriers to adherence concerns due to costs,” she says. “Within the ambulatory care setting, pharmacists are becoming integrated both at the patient care and administrative levels to combat rising prescription costs.”

Joan Vos MacDonald is a healthcare journalist and a regular contributing editor.
Each year, approximately 200,000 children ages 17 years and younger land in emergency departments (EDs) from adverse drug events (ADEs). Children younger than 5 years of age are most likely to visit the ED for ADEs, according to the CDC.

Adverse drug events (ADEs) are a leading cause of injuries and death in children in the United States, and psychotherapeutic agents such as antidepressants and central nervous system (CNS) stimulants have been implicated in rare, but serious, side effects such as suicide, serotonin syndrome, and death. Pediatric CNS stimulant prescriptions have skyrocketed 483% from 1990 to 2015, according to an October 2016 *New York Times* article. The increasing number of prescriptions is raising concerns regarding the potential overprescribing and unnecessary prescribing of stimulants and other psychotropic medications in children.

Pharmacists who are involved in patient care, including community pharmacists, have unique opportunities to manage patients and help improve safety outcomes. “Pharmacists play a critical role in ensuring evidence-based prescribing of psychotropic medications, identification, and management of drug interactions, and monitoring of side effects,” says Danielle Stutzman, PharmD, BCPP, a psychiatric pharmacist at Children’s Hospital Colorado in Aurora.

**Polypharmacy Problems**
Part of psychotropic medication management includes limiting the effects of psychotropic polypharmacy, defined as taking more than one psychotropic medication that offers the same therapeutic effect. Stutzman says several factors contribute to polypharmacy in pediatric populations taking these medications. They include:

- **Misconceptions** regarding the onset of clinical effect such as in the case of antidepressants that take several weeks to see their full effect.
- **Poor understanding** of specific symptoms clinicians hope will improve after initiating psychotropic therapy.
- **Inadequate knowledge** of side effects associated with these medications. Stutzman says this is especially problematic in certain subpopulations, such as children diagnosed with autism spectrum disorder who are less likely to tolerate antidepressants and may actually have worsening mood and increased irritability.

**Population-Specific Considerations**
Many psychotropic medications have not been approved by the FDA for use in children, but they are still frequently prescribed for them. Pharmacists should be aware of this trend as well as how these medications behave differently in children than adults.

“An important piece to remember is that we cannot necessarily apply pharmacologic treatment principles in psychiatry to pediatric patients,” cautions Stutzman. She adds that off-label prescribing also increases children’s risk for polypharmacy because psychotropic medications can have different responses in children than in adults.

Equally as important is that pharmacists recognize that certain populations—such as foster children and children from lower-income families—are at greater risk for polypharmacy than others. Evidence-based medicine offers the best weapon to counter this challenge, but pediatric studies are insufficient, says Takesha Cooper, MD, MS, assistant professor of psychiatry at the UC Riverside School of Medicine. “The lack of pediatric studies is a plug for the need to do more pediatric research,” says Cooper.

**What Pharmacists Can Do**
Pharmacists can help combat polypharmacy by identifying a single psychotropic medication indicated for several psychiatric conditions, Stutzman says. They can also use established state guidelines to help develop and implement protocols for prescribing psychotropic medications and monitoring their levels, labs (for example, lipid panels and A1c), and assessing extrapyramidal effects.

Charles Caley, PharmD, BCPP, clinical professor and chair of pharmacy practice
at Western New England University College of Pharmacy and Health Sciences in Springfield, MA, says pharmacists can leverage their specialized knowledge of pharmacokinetics to improve patient safety when evaluating the potential for pharmacokinetic interactions—especially for children who may have psychiatric illness such as bipolar disorder, ADHD, and anxiety.

For example, a pharmacist’s understanding that antidepressants such as fluoxetine, bupropion, and paroxetine inhibit the CYP2D6 pathway is helpful when a child taking any of these drugs receives a new prescription for Adderall. Since Adderall is metabolized via the CYP2D6 pathway, medications that inhibit this pathway would increase potential Adderall-related drug side effects such as hypertension, increased heart rate, tic-like movements, and seizures. In this situation, Caley recommends reducing a child’s Adderall dose by 50%.

Finding Balance
Keenly aware of public concerns regarding over- and inappropriate prescribing, Cooper points out that medication is not the only first-line treatment, but that medication is necessary for some children depending on their manifestations.

Older evidence suggests that some children with behavioral health issues may actually be undertreated. According to a 2014 post by former director Thomas Insel at the National Institute of Mental Health, 4.2% of the 7.5% of children taking prescription medications are taking psychostimulants, but 11% of children have received a diagnosis of ADHD. This statistic suggests some children may not be receiving pharmacological treatment for psychiatric disorders. While psychotropic medications can serve as first-line, concomitant, or second-line treatment, pharmacists should also recognize that nonpharmacological management such as psychotherapy also plays a significant role in improving symptoms in patients. Psychotherapy includes weekly talk therapy, skill-building, cognitive ability, and helping children think through situations—such as strategies for coping with urges for self-injury.

“The pill doesn’t teach the child anything ... It’s the psychotherapy that teaches skills to cope, so it’s important to work with therapists to ensure children’s needs are being met.”

TAKESHA COOPER, MD, MS

The percentage of adverse drug events in children that are caused by supratherapeutic effects from ingesting either suitable or excess doses of a single psychotherapeutic medication.


37%

Education Is Key
Negative perceptions also contribute to medication-related challenges in behavioral health and create additional barriers to patient treatment and recovery while diminishing the quality of physical care patients with psychiatric conditions receive, according to a 2013 *JAMA Pediatrics* article, “Medication Use in US Youth with Mental Disorders.”

Caley emphasizes that negative mindsets can have exceptionally deleterious impacts in community pharmacy because of its degree of patient accessibility. “Pharmacists need to be reflective and feel confident about addressing psychotropic medications,” he says. “It’s important to acknowledge that there’s a stigma or unwillingness to address mental illness in children and other populations among community pharmacists because there’s a lack of comfort in discussing this topic.”

Pharmacists should acknowledge their discomfort in discussing behavioral health issues with patients and parents of children with these challenges, Caley says. They should seek additional education and training to become more comfortable with their roles in addressing psychotropic challenges in children. The American Academy of Child and Adult Psychiatry offers a prescribing guide and other resources.

“Psychotropic illnesses are brain illnesses which are influenced by many other things—the environment, perceived stress, genetics,” says Caley. Pharmacists need to have more than a casual familiarity with these medications.”

Frieda Wiley, PharmD, BCGP, is a regular contributor. She writes for several medical magazines and serves on the American Medical Writers Assn. National Communications Committee.
In Western North Dakota, Jody Doe, RPh, has spent the past 23 years operating the Killdeer Drug Store in the small town of Killdeer, population under 1,000.

“This is the only pharmacy in the whole county—it’s more than an hour away from the next one—and it’s a service that’s needed here,” Doe says. “I enjoy providing the service and helping people out. I’m here every day so I know what’s going on and I can provide a personal touch that those in other areas of the country can’t.”

After pharmacy school, Doe worked as a pharmacist in bustling Portland, OR, but returned to rural North Dakota because he missed the small-town atmosphere he was raised in.

Independent pharmacists in rural America like Doe are vital to the residents who live in these small communities. But they are becoming increasingly rare, as challenges force them to shut down.

The RUPRI Center for Rural Health Policy Analysis at the University of Iowa released a policy brief this year that revealed more than 16% of the independently owned rural pharmacies in the United States closed between March 2003 and March 2018, lowering the number to just 6,393.

Among the worrisome findings of the report was the disappearance of retail pharmacies in some rural communities altogether, with the data showing that 630 rural communities that had at least one retail pharmacy in March of 2003 no longer had one in March of 2018.

Recent analysis by the National Council for Prescription Drug Programs revealed that independent pharmacies, which represent 52% of all rural retail pharmacies, are often the only operating pharmacy in a community, with the data showing that more than 1,800 independent community pharmacies are the lone source in a particular rural area. And because 1,231 independently owned rural pharmacies have closed over the last 16 years, this is alarming.

And it’s not just the independent rural pharmacies suffering. Many rural hospitals and chains are finding it hard to find staff pharmacists willing to live in rural areas.

Rural Pharmacy Challenges
Rural pharmacies are forced to shut their doors for many reasons. Keith Mueller, PhD, director of the RUPRI Center for Rural Health Policy and principal investigator in rural pharmacy closures, says for one, the costs they pay to drug manufacturers per prescription are higher than their urban counterparts. This is because they purchase less at a time, and since they tend to sell less volume as well, their profits tend to be smaller. Plus, with increasing competition from internet suppliers, where prices are lower because they deal in bulk supplies, many are not getting the customer base needed to survive, he says.

Mike Swanoski, PharmD, BCGP, FASCP, associate professor of pharmacy practice and pharmaceutical sciences, University of Minnesota College of Pharmacy, says the decline in rural pharmacies is primarily due to declining reimbursements for medications dispensed as reimbursement rates are often barely enough to cover the cost of the medication.

Still, he says, the rural pharmacy is a lifeblood of small-town America.
Rural Pharmacists Explain the Draw

Jennifer Laws, BSPS, CPhT, grew up in a town of 1,822 people and started volunteering in a rural hospital pharmacy in high school. Although she headed to Kansas City to begin her career, she always knew she wanted to come home and work in a friendlier, more deep-rooted community.

“I worked in the Kansas City area for 11 years before moving back to my hometown and am currently working in a neighboring critical access hospital,” she says. “The benefits of rural areas are getting to know more about your customers and having a presence in the community. The biggest con is the lack of coverage for days off and vacations, so it becomes a 24/7 job.”

When Laws does need time away, a pharmacist in the general vicinity covers her shifts.

The career of Mike Swanoski, PharmD, BCGR, FASCP, includes more than 20 years of practicing in a small town or neighborhood pharmacy.

The biggest payoff, he says, was getting to know his customers extremely well. “The trust and confidence my patients placed in me as their pharmacist was the highest honor I could ever hope to achieve and one that I was professionally obligated to continually and consistently earn,” he says. “I was fortunate to practice in a setting in which I was able to spend the necessary time with each patient to assure their needs were met and there questions answered.”

Mike Swanoski, PharmD, BCGR, FASCP, 16 years at Scotland County Hospital in Memphis, MO, a city with a population of 1,822.

The main challenge is the lack of pharmacists willing to move to rural areas,” she says. “Unless they have a tie to the specific rural area, most pharmacists will take higher paying jobs in metropolitan areas,” she says. “Rural pharmacies also struggle with declining reimbursement amounts from PBMs, which is another detriment.”

Nicholas Herrmann, PharmD, pharmacist in charge at Memphis Community Pharmacy in Memphis, MO, agrees staffing is a huge challenge.

“It is even more difficult to find part time or per diem staff,” he says. “If a position doesn’t offer enough guaranteed hours, sometimes the closest people you can find are from more metropolitan areas, which means paying higher rates for things like drive time and hotel accommodations.”

Reimbursement and staffing aren’t the only challenges rural pharmacists face. Many feel isolated because they are often the lone person working, and there are rarely colleagues nearby to share information and talk about what’s happening in the pharmacy industry, according to Mueller.

He adds it’s also harder to get time off to go to a conference or attend advanced educational classes with fellow pharmacists because there’s no one to cover the time away and the venues are usually too far for a quick trip anyway.

Overcoming Barriers

Herrmann notes there are some benefits to pharmacists who work in these areas.

“It allows the pharmacist to take a more prominent place in the community as a whole,” he says. “Also, it makes knowing your patients that much easier and more important.”

As for the financial challenges, Swanoski says pharmacists in these areas should consider expanding the scope of healthcare provided at their pharmacies to include: comprehensive medication management, which is a covered service under Part D Medicare, immunizations, and medical supplies.

“They should explore opportunities for providing medications to patients residing in assisted living or skilled nursing facilities,” he says.

Pharmacists in rural areas might also consider how to expand their offerings by using technology. When telepharmacy became legal in North Dakota, Doe opened two remote locations there: one, 56 miles away in the city of Beach and the other, 95 miles away in the city of New England.

Thanks to his live video sessions, Doe can have face-to-face interactions with customers and monitor and supervise an onsite pharmacy technician at each location who is tasked with counting and distributing the medications.

“It’s been a good thing, and people support it well,” he says. “It’s like I’m virtually there, and it’s a service that was desperately needed.”

Keith Loria has been writing for major newspapers and magazines for nearly 20 years.
As drug costs continue to increase at an unsustainable rate, many industry insiders believe the current trajectory of pharmaceutical expenses will eventually bankrupt the U.S. healthcare system. Girish Dighe, PharmD, MS, director of pharmacy, business services, at OhioHealth, a not-for-profit system of hospitals and healthcare providers in Columbus, notes that there are fundamental flaws within the healthcare system that cause vastly complex challenges to drug pricing.

“The multitude of stakeholders involved in the drug channels for bringing patients access to medications (manufacturers, insurers, pharmacy benefit managers [PBMs], providers, retail pharmacies, wholesalers) revolves around financial incentives driving each stakeholder,” Dighe says. “The growing spread between pharmaceutical list price and net price negotiated by drug channel stakeholders has negatively impacted patients’ out-of-pocket costs.”

According to a recent survey from NORC at the University of Chicago and the West Health Institute, 75% of Americans believe prescription drug prices are unreasonably high.

President Donald Trump took a big stand against rising drug prices early in his tenure, and since then some drug companies—Pfizer, Novartis, Sanofi, Roche, and Merck among them—have announced that they’re freezing or even lowering drug costs. Although those pledges seem to be short-lived.

Alex Azar, HHS secretary, recently announced that the administration is also working to stop drug rebates to PBMs.

The Pharmaceutical Care Management Association (PCMA), which represents PBMs, issued a report recently blaming high drug prices on drug makers, not PBMs.

In the report, Mark Merritt, PCMA’s president and CEO, said the findings supported the belief that drug makers set and raise prices unrelated to the rebates they negotiate with PBMs.

“Drug companies keep raising prices even when rebates go down,” he says. “Simply eliminating plans’ ability to negotiate price concessions would enrich drug makers at
the expense of patients, who would not only face higher prices, but also higher premiums and out-of-pocket costs.”

Amy Beatty, PharmD, BCPS, OhioHealth’s clinical director of pharmacy services, says medication shortages are to blame for some drug price escalations. “When lower-cost generic medications enter shortage status, providers are faced with selecting more expensive alternatives,” she says. “This pattern of drug shortages has continued to the point where many organizations are now funding positions and teams to manage the fragile supply chain.”

As drug costs continue to escalate, many hospitals worry about access to important medications because they cannot always get what they need when they need it. That’s why many hospitals, such as OhioHealth, have begun rationing drugs in certain situations, and some larger healthcare systems have even started a company, Civica Rx, to produce their own medications to address both cost and supply concerns.

Earnest Alexander, PharmD, assistant director, clinical pharmacy services, Tampa General Hospital, a teaching hospital for the USF Health Morsani College of Medicine, notes that hospitals and pharmacy departments work closely with group purchasing organizations, which negotiate lower drug prices for member organizations, to monitor and attempt to predict inflation trends. This isn’t an exact science and can vary based on several factors, such as changes in formulary and clinical practice, drug shortages, and alterations in competition in the marketplace for drugs.

For example, a decade ago, yearly inflation would range 3% to 5%, Alexander says. In the last five years, this has more than doubled to 8% to 12% increases in cost yearly. “Interestingly, the number of drug shortages has skyrocketed in the past five to 10 years, resulting in decreased supply and sharply climbing costs for the remaining drugs available for patient care,” Alexander says. “Challenges exist because there is a constantly shrinking margin, which poses operational issues for facilities.”

John M. Allen, PharmD, clinical assistant professor, College of Pharmacy, University of Florida, says rising drug costs are certainly not a new phenomenon; however, the price has risen recently for several medications that have few alternatives and that are commonly used in the care of critically ill patients, including epinephrine, vasopressin, and calcitonin. Historically, these agents had relatively low prices and minimal cost increases year after year.

“Hospital pharmacies routinely monitor for changes in drug pricing and evaluate different ways to mitigate the impact of increasing drug prices without sacrificing patient care,” he says. “Some strategies may include establishing criteria for using more expensive drugs, development of order sets to drive appropriate use, and prospective drug audits.”

Here are some other avenues that hospitals are exploring to alleviate high costs.

1. Proper Use of Drugs

When price simply cannot be negotiated, appropriate use of drugs is the
only pathway to manage escalating drug costs, says Linda Huang, PharmD, OhioHealth’s medication utilization coordinator for pharmacy services.

“First, the [pharmacy and therapeutics] committee must agree upon what appropriate use is,” she says. “The classic use strategies for formulary management are either to deny the drug, deny the drug and use an alternative that provides similar outcomes at a lower cost, or to add the drug but apply restrictions for use around the type of ordering provider, indication, dosing, site of care, and/or other qualifiers in order to guide appropriate use.”

Still, guaranteeing the success of use restrictions can be difficult and labor intensive. It requires a willingness from the providers to agree with these restrictions as well as vigilance from front-line pharmacy staff to uphold restrictions and/or be comfortable with making judgments around use if a scenario occurs outside of the restrictions.

“We have been most successful with use strategies when we can build logic into our EHR to naturally guide physicians toward appropriate use; when we have partnered with our ordering providers to develop accepted restrictions; and when there is transparency and accountability around appropriate use,” Huang says. “Traditionally, monitoring use to ensure a strategy is successful has been a very manual process, but data-management tools can help make this process more automated.”

2. Create a Specialty Pharmacy
Sentara Healthcare, based in Virginia, saw a significant potential opportunity to increase revenue and streamline services and costs to make high-cost drugs more accessible to patients. It decided to retain specialty pharmacy revenue and margins within the Sentara Healthcare system by creating Proprium Pharmacy, its own specialty in-house pharmacy.

“The program was successfully implemented with an impact of $10.7 million annualized,” says Chris Tagliente, PharmD, system director of pharmacy clinical programs at Sentara. “During this implementation, they met all operational timelines and kept clinical patient support and customer satisfaction levels high. They were also able to successfully integrate and train an entirely new set of staff, overcome space availability obstacles, and navigate through several internal transitions and changes in pharmacy state licensure.”

As a result of internally distributing these specialty medications, Proprium Pharmacy has successfully and drastically increased revenue, managed costs, and made these drugs more accessible to patients, he says.

“The Proprium Pharmacy has opti-
mized the patient experience through the integration of clinical activities to help create a better patient experience and reduce overall costs for both the hospital and patient,” Tagliente says. Proprium Pharmacy has also helped to sustain customer satisfaction of greater than 97% with virtually no customer complaints, and improved medication adherence to an overall rate of 93.7%.

3. Use Pharmacogenomics
Houda Hachad, PharmD, chief science officer at Translational Software Inc., which provides recommendations based on genetic data to more than 20,000 clinicians, says DNA-guided prescribing/pharmacogenomics (PGx) is a great way to improve treatment efficacy and costs.

“We now have data that shows if you implement pharmacogenetic approaches in different specialties, they result in optimizing different metrics that can be used to assess medication optimization,” Hachad says. “These include fewer emergency room visits and fewer hospitalizations, and some of them have shown reduction in total costs compared to standard approaches.”

She explains that using genetic tests can help healthcare workers ascertain the best medication and appropriate dosage based on a patient’s DNA before prescribing, which not only improves the effectiveness of treatment, but lowers drug costs by identifying the medication that works best for each patient.

Hachad codeveloped a PGx knowledgebase and a drug interaction database that are used by pharmaceutical companies, regulatory agencies, commercial laboratories, and academic healthcare organizations.

4. Consider Analytics
Analytics can help healthcare systems monitor drug costs and find opportunities to reduce spending without reducing quality of care. Western Maryland Health Systems (WMHS), which offers healthcare services in Allegany and Garrett counties in Maryland and surrounding counties in West Virginia and Pennsylvania, presents an excellent example.

It began using Dimensional Insight’s Diver platform after the cost of the IV form of acetaminophen jumped 250%, to $35 per vial, says George Dealy, vice president of healthcare applications at the analytics company. It used the platform to examine whether the IV drug actually produced better outcomes than the oral version, justifying the increased cost.

After examining various surgical procedures, patient lengths of stay, and number of opiates given, WMHS found no significant difference in patient outcomes with IV acetaminophen, says Dealy. As a result, the health system sharply decreased the amount of the drug it purchased, reducing its spending by 78% over two years, from nearly $250,000 in FY2015 to just over $55,000 in FY2017.

5. Analyze Cost Data
Alexander says the most critical step to dealing with escalating drug costs is a proactive review of the spend/cost data that can aid in spotting issues and altering purchasing on an ongoing basis.

“For example, identifying the best price available for agents along with benchmarking prices is a critical ongoing step in the assessment,” he says. “Because there is constant fluctuation and changes within the market, this requires increased resources within the pharmacy department devoted to purchasing and business analysis.”

These resources can be leveraged to

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**Will biosimilars reduce specialty drug costs?**

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**SPECIAL REPORT**

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mized the patient experience through the integration of clinical activities to help create a better patient experience and reduce overall costs for both the hospital and patient,” Tagliente says. Proprium Pharmacy has also helped to sustain customer satisfaction of greater than 97% with virtually no customer complaints, and improved medication adherence to an overall rate of 93.7%.

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These resources can be leveraged to
create competition through comparable analysis of agents and also through contract maintenance, he says.

Allen adds that knowing a facility’s drug spend, particularly those medications that account for most spending, and being aware of recent trends can help facilities develop plans to curb inappropriate or unnecessary drug use.

“Having data for the prescriber level can also help to identify opportunities to engage with individual clinicians,” he says. “Peer institution benchmarking is helpful to gain insight on potential opportunities for reducing drug spend.”

Allen says another proven method shown to improve care and reduce both drug and overall hospital cost is a robust antimicrobial stewardship program.

“Many institutions now use electronic surveillance programs to promote streamlined antimicrobial use and reduce the development of antimicrobial-related adverse events such as *Clostridium difficile* infection, or multidrug resistant infections,” he says. “Investment in these types of surveillance programs to strengthen your antimicrobial stewardship program can generate a significant return on investment for some facilities.”

6. **Diversify Manufacturers**

For many hospital and healthcare systems, managing the supply chain of pharmaceutical sourcing and contracting is a key focus area for drug cost savings.

OhioHealth, for example, has found that multiple vendor contracting has demonstrated effective cost management and flexible options for sourcing.

“In today’s environment, drug shortages continue to burden drug channels and access,” Dighe says. “Ensuring a robust supply chain will keep health systems in a strong position to identify the most cost-effective drug sourcing opportunities, while continuing to drive high-quality healthcare delivery.”

7. **Use market Intelligence**

Huang also recommends staying current on what is coming down the pipeline in terms of new products, biosimilars, and generics.

“The traditional method of finding this information is by enrolling in multiple listservs and newsletters from the FDA, national group purchasing organizations, wholesale drug distributors, and/or national medical or pharmacy organizations,” she says, warning that a lot of this information is incomplete and requires a lot of labor to piecemeal from multiple sources to understand the changing landscape.

“Our health system chose to subscribe to a third-party market intelligence company that provides a database of pipeline information (ie, new products or alternatives, projected launch dates and probability, competitive strategies, etc.), as well as medical experts to help digest this into actionable information,” Huang says.

8. **Explore Automation Technology**

A recent strategy employed at Tampa General is intravenous compounding automation/robotic technology, which allows facilities to move away from more expensive ready-made products and shift toward an internally compounded product that is purchased in bulk.

“There is a learning curve associated with this technology, and it’s a capital expense that requires budgetary approval,” Alexander says. “Also, it is important to note that the return on investment can occur quickly, in a matter of months, due to flexible financing options, such as hardware leases instead of upfront out-of-pocket hardware purchases.”

Allen adds that increasingly, hospitals are scrutinizing the use of high-cost biological agents in their outpatient infusion centers. Many of these agents can be administered in a physician’s office and do not require administration via an outpatient infusion center.

“Completing a profit/loss evaluation on specific high-cost biological agents, with potential re-evaluation of formulary status, can be another way for hospitals to reduce the impact of rising drug costs,” he says.

9. **Encourage Medication Use Initiatives**

OhioHealth’s Beatty notes that the healthcare system recognized several years ago that managing medication costs solely through contracting, inventory strategies, and substitutions would not provide the cost-effective care that would be needed in the future.

“Health systems need to be willing to look at and capture cost-avoidance through medication use initiatives,” she says. “These initiatives should look at the right medication for the right patient for the right reasons; executing on this tactically can take many forms.”

For instance, the electronic medical record can help drive decision making, or focused project groups might dig deep into a specialty area.

“We have found clinical pharmacists and coordinators to be a key component of our use strategy,” Beatty says. “These pharmacists work alongside prescribers and help manage the medication plan, including evaluating less-costly alternatives that will retain or improve quality. This is especially necessary in complex fields like oncology, critical care, or infectious disease.”

*Keith Loria is a business journalist who has written for major newspapers and magazines for 20 years.*
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Within the next five years, people with diabetes will wear sensors that will alert them to healthy food choices when they arrive at a restaurant, predicts David Klonoff, MD, medical director of the Diabetes Research Institute, Mills-Peninsula Medical Center in San Mateo, CA.

The GPS-based technology, says Klonoff, will be preprogrammed with dietary preference information based on a sound diet that is less likely to raise blood glucose levels and leads to slightly lower A1c levels and complications.

Klonoff also projects more widespread use of continuous glucose monitors (CGMs) that include alarms with personalized notifications. The alarms signal for very low or very high glucose levels before they become dangerous and, as a result, reduce the incidence of hospital admissions for hypoglycemia. Eventually, CGMs also will decrease the rates of admission for chronic complications of diabetes related to high glucose levels, such as heart attack and kidney failure, he says.

CGM technology will also become more portable, accurate, last longer, require less calibration, and yield more decision support, according to Klonoff. “The technology will gradually push self-monitoring of blood glucose out of the marketplace for about half of patients who currently use it.”

Michael LeMay, MD, an endocrinologist at Hartford Hospital in Hartford, CT, agrees that CGM devices will continue to evolve and improve. Already, the latest CGMs are more portable and powerful than first-generation models, he says. They’re also easier to use and the science behind them is exponentially more accurate

In addition to an alarm that alerts users to high or low glucose levels, he says CGMs may include features such as:

- The ability to record (based on user input) meals, physical activity, and medicines;
- The ability to download data to a computer or smart device so trends can be monitored more easily; and
- The ability to immediately transmit information to the smartphone of a parent, partner, or caregiver.

Wide-Scale Use

According a survey of 339 patients and healthcare providers that appeared in Diabetes in Control in March, 39% of patients with type 1 diabetes are using CGMs and healthcare providers see a steady upward trend in their adoption. In fact, providers who took the survey estimate that 77% of their type 1 patients will be using CGM five years from now.

Practitioners believe CGM usage in patients with type 2 diabetes will soar in the next five years. Currently, they estimate 11% of these patients are using
CGMs; in five years, they expect that will increase to 46%.

But according to Schafer Boeder, MD, Division of Endocrinology, at the University of California, San Diego, only about 15% to 20% of patients with type 1 diabetes—and a much smaller percentage of patients with type 2 diabetes—in the United States, are believed to be using a CGM.

“Cost is a major barrier, though lack of familiarity by both patients and providers is also an issue,” he says.

Although LeMay encourages patients to use CGMs, issues like insurance coverage prohibit some from doing so. “I’ll give a patient a sample sensor, which they get used to and love, but when they try to put in a prescription for it, they find it’s too expensive. Sometimes, insurance companies lag behind.”

Chuck Green has covered healthcare for more than 10 years.

The Artificial Pancreas

**BY KAREN APPOLD**

Medtronic released its MiniMed 670G automated insulin delivery pump in 2017, a major step toward a fully automated insulin delivery system (also known as an artificial pancreas), for type 1 diabetes patients. “This is the first commercially available device to use continuous glucose monitoring information to adjust insulin doses,” says Anders L. Carlson, MD, medical director, International Diabetes Center. “Using an algorithm inside the insulin pump, the system adjusts insulin doses up or down accordingly to target a healthy glucose level.”

Data show improved average diabetes control, more time spent in a more ideal blood glucose range, and fewer blood glucose readings in the low range. “This is important because both high and low glucose are associated with significant complications and costs,” Carlson says. Hypoglycemia hospital admissions from the emergency department, for instance, cost an average of $1.2 billion per year, so any technology that prevents levels from going too low is a major advancement.

Carlson says the next step would be to create a fully “closed loop” device, rather than a “hybrid closed loop” device, which will be smart enough to give a quick burst of insulin when the patient eats without having to tell the device that they are going to eat something. Currently, patients must enter their blood glucose and amount of carbohydrates they estimate are in a meal. Then, based on programmed settings, the pump delivers an appropriate burst of insulin. To close the loop, the device would need to be able to handle that rapid increase in blood glucose following a meal or snack. Several groups are working on this, and newer systems may involve other hormones in addition to insulin being placed in the insulin pump.

**Impact on Hospitalized Patients**

David Klonoff, MD, of the Diabetes Research Institute, Mills-Peninsula Medical Center, San Mateo, CA, expects hospitalized people with diabetes to be treated with a combination of hardware and software advances that are uncommon in hospitals today. Patients will be fitted with a rapidly equilibrating CGM device, and insulin doses will be ordered by software programmed with their outpatient daily insulin dose, insulin sensitivity factor, and carbohydrate-to-insulin ratio, he says. This process will culminate in tighter mean glycemic control with less hypoglycemia, and translate into lower costs, as well as a reduced length of hospitalization.

Schafer Boeder, MD, Division of Endocrinology, at the University of California, San Diego says use of CGM in hospitals—even for those not on CGM as outpatients—is an area of active research. If CGMs can reduce inpatient hypoglycemia events, decrease complications, shorten hospital stays, and/or reduce readmissions, it may become a standard technology in the hospital.

“**The technology will gradually push self-monitoring of blood glucose out of the marketplace for about half of patients who currently use it.**”

DAVID KLONOFF, MD
Dacomitinib Approved for Non-Small Cell Lung Cancer

In September, the FDA approved dacomitinib (Vizimpro, Pfizer), a second-generation selective nonreversible inhibitor of epidermal growth factor receptor (EGFR), as a first-line therapy for patients with metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R substitution mutation detected by an FDA-approved test.1

EGFR is a transmembrane protein growth-signaling receptor. It’s over expression has been implicated in numerous human cancers with most prominence in lung, head and neck, and glioblastomas.2

Efficacy

Approval of dacomitinib was based on a randomized controlled multicenter open-label clinical trial enrolling 452 patients with unresectable stage IIIIB/IV EGFR-positive NSCLC (ARCHER 1050).3 The ARCHER trial consisted of two arms comparing safety and efficacy of dacomitinib versus gefitinib, a previous first-line therapy option for EGFR-positive NSCLC.

Patients in the dacomitinib arm received 45 mg by mouth daily, while gefitinib was dosed at 250 mg by mouth daily. The primary outcome measure was progression-free survival (PFS) as determined by blinded Independent radiological central review panel.

To be enrolled in the trial, patients had to have an Eastern Cooperative Oncology Group performance status score of 0 or 1. They also had to have no prior therapy for metastatic disease or be at least 12 months without recurrent disease.

The trial showed improvement in median PFS at 14.7 months (95% confidence interval [CI], 11.1-16.6) in the dacomitinib arm and 9.2 months (95% CI, 9.1-11.0) in the gefitinib arm (hazard ratio [HR], 0.59; 95% CI, 0.47-0.74; p=0.0001). Median duration of follow-up for progression-free survival was 22.1 months (95% CI, 20.3-23.9).2

Overall survival was also improved, with a median overall survival time of 34.1 months with dacomitinib compared with 26.8 months with gefitinib (HR, 0.76; 95% CI, 0.582-0.993, p=0.44).4

Safety

Of the 227 patients who received dacomitinib, 27% experienced serious adverse reactions. The most common adverse events reported included diarrhea (87%), paronychia (61%), acneiform rash (49%), stomatitis (44%), decreased appetite (31%), dry skin (27%), decreased weight (25%), alopecia (24%), cough (21%), and pruritus (20%).1 Interstitial lung disease (ILD, 0.4%) and grade 3 diarrhea (8%) were the two side effects that most frequently resulted in discontinuation of the study drug.

For patients developing respiratory symptoms (cough, shortness of breath) indicative of possible ILD, dacomitinib should be held.5 If these symptoms worsen (exertional dyspnea, fever) or ILD is confirmed, treatment should be permanently discontinued.

Patients who develop grade 3 to 4 diarrhea should have their medication held until symptoms resolve and then should be restarted at the same or lower dose. Diarrhea should be treated at the onset with antiarrheals (loperamide or diphenoxylate hydrochloride/ atropine sulphate).5

Dacomitinib exhibits a drug-drug interaction with proton pump inhibitors, which should be discontinued; histamine-2 receptor antagonists and antacids are permitted. Medications that are cytochrome P450 CYP2D6 substrates also exhibit interactions with dacomitinib and should be avoided as concomitant usage can cause elevated medication levels.

Females with childbearing potential should be advised to use effective contraception while taking, and for at least 17 days after discontinuing, dacomitinib.

Dosing

Recommended dosing for dacomitinib is 45 mg daily by mouth, with or without food. If a dose is missed, or vomiting occurs shortly after taking, another dose should not be taken. Patients should resume with the next scheduled dose of the medication.

This medication is available in 15-mg, 30-mg, and 45-mg formulations.5

Matthew J. Hadfield, DO is an intern in internal medicine at UConn Health. Lisa M. Holle, PharmD, BCOP, FHOPA, is associate clinical professor with the University of Connecticut School of Pharmacy in Storrs.

REFERENCES

Job Satisfaction Is A Choice

I don’t see my patients as interruptions to what I am doing. I see my patients as what I am supposed to be doing.

PETE KRECKEL, BSPharm, practices independent community pharmacy in Altoona, PA. He welcomes your e-mails at pharmcanoe@aol.com

It was twenty years ago this summer, in 1998, that my wife and I attended a drug company-sponsored event in State College, PA, and were delighted to run into two of our classmates from the class of 1981. One is a well-known clinical pharmacist for a health system about one hour from our home. He is an outstanding pharmacist, mentor, and teacher. His skill set is acute care, and he’s an expert with respect to acid-base balance in the intensive care unit.

The other classmate is the director of pharmacy of an area hospital. Both guys are top-flight pharmacists. The conversation quickly changed to community pharmacy. Both were insistent that by 2008, there would be no such thing as a retail pharmacy. “By then there will be kiosks setting around, and the patient will walk up insert a card and their meds will drop out, just like buying a soda from a vending machine.”

I asked, “So how will these prescriptions get into the machine?” Their answer “Robots—by 2008 this profession will be so automated, there will be no reason to have a human involved.”

I must say these two guys really got my attention. I think of our conversation frequently, and just shake my head. We are 10 years past that prediction of what was to occur in 2008, and our patients in the community setting are needier than ever. My patients can’t (or won’t) use the Interactive Voice Response system to order their refills. They simply press “0” to talk to someone, and then frequently say “Just get everything ready.” The patients don’t have prescriptions numbers, or even drug names. We won’t even mention insurance card issues, prior authorizations, adherence, or even the refill status of their prescription. Our patients simply can’t navigate the ever-complicated healthcare system.

I do see the frustration of my fellow pharmacists practicing in the community setting. Low reimbursements, overwhelming workloads, reduction in staffing and long hours make many pharmacists less than satisfied with their career choice. I keep my sanity by thinking of all the patients I help with effective patient counseling and with the wonderful relationships I’ve developed with both the local physicians and patients.

I make every attempt to practice “at the top of my license,” by always networking with other professionals, learning the latest information, and teaching future pharmacists and physician assistants, all for the benefit of my patients. If I don’t, I could easily be disgruntled with the numerous shortcomings of this profession. I often tell my student pharmacists that the attractive salary or “golden handcuffs” is one of the biggest challenges of this profession. Because of the salaries this profession commands, we seem to put up with understaffing, lack of lunch breaks, and even the day-to-day hassles from physicians, patients, and management just because of what is printed on our W-2 form at the end of the year.

I don’t see my patients as interruptions to what I am doing. I see my patients as what I am supposed to be doing. They are my reason for going to work. They are why I put on a clean ironed shirt (thanks to my attentive wife, Denise), wrap a Pancaldi tie around my neck (thanks to a pharmacist friend Jerry), put on my white lab coat, and open the drug store.

When 9 a.m. strikes, the phone rings off the wall, patients have tons of questions, lots of interventions, and patient interactions remind me that I won’t be replaced by a robot any time soon. Throw in a couple of immunizations, and I quickly realize how much my patients need my level of expertise. No doubt in the next 10 years that none of my brothers or sisters in the community pharmacy will be replaced by a vending machine!
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