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Researchers are testing a novel method to combat potential new flu pandemics and to treat influenza. They are targeting the receptors on cells that the virus uses to gain entry to the body.

In a report published in the Jan. 25, 2019, issue of *Journal of Immunology*, researchers at the Liverpool School of Tropical Medicine in the United Kingdom explained how they engineered a part of an antibody to target the viral proteins that allow flu to mutate and become deadly.

New drugs to combat influenza are needed because influenza outbreaks account for between 300,000 and 650,000 respiratory deaths globally each year, mostly in children and the elderly, says study author Richard Pleass, PhD, professor and chair of parasite immunology at the school, in a statement.

"Better anti-influenza therapeutics are urgently needed. The transfer of antibodies from people recovering from influenza during the 1918 and 2009 pandemics reduced mortality from influenza by 50% and 26%, respectively."

Influenza vaccines have limited public health impact during a pandemic, and current influenza vaccines are less effective than the vaccines used against other infectious diseases, Pleass tells *Drug Topics*.

"This is because influenza viruses that circulate in human and animal populations mutate two key viral surface proteins, hemagglutinin (HA) and neuraminidase (NA), thus allowing them to escape from protective antibodies produced through natural infection or vaccination."

Both HA and NA target a sugar called sialic acid, found in abundance on the receptors of cells lining the mammalian respiratory tract, which the virus uses to gain entry into the body. The sialic acid...
acid-binding contacts on HA and NA do not mutate readily, otherwise the virus would not be able to infect human cells, Pless says.

Pless and colleagues engineered antibody Fc (fragment crystallizable) with enhanced sialic acid that target these conserved parts of both HA and NA, binding influenza viruses and blocking their interactions with human cells.

In addition to influenza viruses, these engineered biologicals may also be useful in the control of other pathogens, such as group B streptococci, Streptococcus pneumoniae, Mycoplasma genitalium, and Newcastle Disease Virus.

"To be useful, these antibody medicines (also called FLU-IVIG) need to be manufactured in advance of future epidemics, which is obviously problematic as there may be modest or little neutralizing activity against newly-emerging strains. Therefore, combinations of existing medicines, including FLU-IVIG, with sialic acid blockers could increase their efficacy while future-proofing against the next pandemic," Pless says.

While a new anti-influenza drug could be used as a preventative, it also can be beneficial after the infection starts. "Often what kills you with flu is the ensuing cytokine storm. By binding inhibitory receptors these molecules may dampen such effects," he says.

People who die from influenza are most often killed by a bacterial pneumonia, Pless says. "Interestingly, these bacteria, by nature of being sialylated, can bind directly to influenza viruses that facilitate their entry and spread in the body. These molecules may therefore block this interaction and thus help the body contain the bacteria that actually hasten your death when you have flu."

The modified Fc fragments are suitable both as clinical candidates and for large-scale manufacture, Pless says. "Fc fragments are a well understood class of compound and have even been used to treat idiopathic thrombocytopenia in children. They are also straightforward to manufacture using existing antibody pipelines available for Chinese hamster ovary cells, the manufacturing workhorse of the pharmaceutical industry."

The findings are "at a very early stage and much work still needs to be done before they make it to the clinic," Pless tells Drug Topics. The researchers need to test the molecules in relevant animal models to determine if they have any in vivo efficacy as well as their half-life, safety, pharmacokinetics, and other factors.

The Wellcome Trust provided funding for the research. "This is a fascinating project, and one which could have really far-reaching impact not only for influenza but as a platform technology to develop new medicines for many other diseases that are currently treated by antibodies," says Sara Marshall, PhD, head of clinical and physiological Sciences at the Wellcome Trust.
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 factors,

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

Only VASCEPA has positive CV outcomes data

VASCEPA showed a 25% RRR in CV events

(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 VASCEPA**

- 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.

**References:**


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.
FDA-APPROVED INDICATION AND LIMITATIONS OF USE FOR VASCEPA®

- 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.

IMPORTANT SAFETY INFORMATION FOR VASCEPA FROM FDA-APPROVED LABEL

Data from Two 12-Week Studies [MARINE and ANCHOR] of Patients with Triglycerides Values of 200 to 2000 mg/dL [n=622 on VASCEPA, n=309 on placebo]1

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

IMPORTANT INFORMATION FOR HCPs ABOUT 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] >135 and <500 mg/dL).

- Patients were eligible to enter the trial if they were at least 65 years of age and on stable statin therapy with fasting LDL-C levels of >40 and <100 mg/dL and fasting TG levels of 135 and <500 mg/dL. Patients also needed to have either established CVD (secondary prevention cohort), defined as documented history of coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease, or be at least 50 years of age with diabetes and at least one additional risk factor (primary prevention cohort).
  - Key exclusion criteria included severe heart failure, active severe liver disease, 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 66% 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).

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

<table>
<thead>
<tr>
<th></th>
<th>Placebo N = 6090 (n (%)</th>
<th>VASCEPA N = 6089 (n (%))</th>
<th>VASCEPA vs Placebo Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time to first occurrence of cardiac death, myocardial infarction, stroke, coronary revascularization, hospitalization for unstable angina (5-point MACE)</td>
<td>901 [22.0]</td>
<td>705 [17.2]</td>
<td>0.75 (0.68 - 0.83)</td>
</tr>
<tr>
<td>Time to first occurrence of cardiovascular death, myocardial infarction, stroke (3-point MACE)</td>
<td>406 [14.8]</td>
<td>459 [11.2]</td>
<td>0.74 (0.65 - 0.83)</td>
</tr>
<tr>
<td>Time to cardiovascular death</td>
<td>213 [5.2]</td>
<td>174 [4.3]</td>
<td>0.80 (0.64 - 0.98)</td>
</tr>
<tr>
<td>Time to death by any cause</td>
<td>310 [7.6]</td>
<td>274 [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>0.54 (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>214 [5.3]</td>
<td>0.65 (0.55 - 0.78)</td>
</tr>
<tr>
<td>Time to first coronary revascularization</td>
<td>544 [13.3]</td>
<td>374 [9.2]</td>
<td>0.64 (0.58 - 0.74)</td>
</tr>
<tr>
<td>Time to first hospitalization for unstable angina</td>
<td>157 [3.8]</td>
<td>108 [2.4]</td>
<td>0.68 (0.53 - 0.87)</td>
</tr>
</tbody>
</table>

All prespecified individual and composite endpoints were statistically significant except time to death by any cause.

(1) Time to death by any cause, or total mortality, is not a component of either the primary composite endpoint or key secondary endpoint.

(2) The predefined composite secondary endpoint included emergent or urgent revascularization, the composite of all revascularization was predefined as a tertiary endpoint.

(3) Determined to be caused by myocardial ischemia by invasive/non-invasive testing and requiring emergent hospitalization.

VASCEPA significantly reduced the following:
- the risk for the primary composite endpoint (5-point 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 predominantly (93.2%) moderate- to high-intensity statin use and median baseline LDL-C levels of 75.0 mg/dL.
The Kaplan-Meier estimates of the cumulative incidence of the primary and key secondary composite endpoints over time are shown in Figure 1 and Figure 2 below.

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

![Graph showing estimated cumulative incidence over 5 years for VASEPA and placebo groups.]

No. at Risk
- Placebo: 4090
- VASEPA: 4089

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

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

![Graph showing estimated incidence over 5 years for VASEPA and placebo groups.]

No. at Risk
- Placebo: 4090
- VASEPA: 4089

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

The difference between VASEPA and placebo in median percent change in TG from baseline to Month 4 was -20.1 [p<0.001] and from baseline to Month 12 was -19.7 [p<0.001]. At Month 12, the median [Q1, Q3] TG was 175.0 [122.0, 238.0] mg/dl in the VASEPA group, with 35.9% of patients having TG <150 mg/dl and 61.3% having a TG >200 mg/dl. The difference between VASEPA and placebo in median percent change in LDL-C from baseline to Month 12 was -6.6% [p<0.001]. At Month 12, the median [Q1, Q3] LDL-C was 77.0 [63.0, 94.0] mg/dl in the VASEPA group, with 35.5% of patients having LDL-C <70 mg/dl and 79.9% having LDL-C <100 mg/dl.

**Important Safety Information for VASEPA from REDUCE-IT [n=4089 on VASEPA, n=4090 on placebo]**

- Patients were exposed to VASEPA or placebo for a median of 58 months; 86.9% of patients were exposed for >12 months, 77.2% were exposed for >24 months, 64.6% were exposed for >36 months, 53.6% were exposed for >48 months, 29.5% were exposed for >60 months, and 0.1% were exposed for >72 months.
- Overall adverse event rates were similar across treatment groups.
  - Adverse events and serious adverse events leading to study drug discontinuation were similar to placebo.
  - The one serious adverse event that occurred at a frequency of at least 2% was pneumonia (2.6% in the VASEPA group and 2.9% in the placebo group, p=0.42).

**Treatment-Emergent Adverse Events**

<table>
<thead>
<tr>
<th>Treatment-Emergent Adverse Events</th>
<th>VASEPA N=4089</th>
<th>Placebo N=4090</th>
<th>P value[^1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with at Least One TEAE[^1]</td>
<td>3343 (81.8)</td>
<td>3326 (81.3)</td>
<td>0.63</td>
</tr>
<tr>
<td>Serious TEAE</td>
<td>1252 (30.6)</td>
<td>1286 (30.7)</td>
<td>0.98</td>
</tr>
<tr>
<td>TEAE Leading to Withdrawal of Study Drug[^2]</td>
<td>321 (7.9)</td>
<td>395 (9.8)</td>
<td>0.40</td>
</tr>
<tr>
<td>Serious TEAE Leading to Withdrawal of Study Drug[^2]</td>
<td>88 (2.2)</td>
<td>88 (2.2)</td>
<td>1.00</td>
</tr>
<tr>
<td>Serious TEAE Leading to Death[^2]</td>
<td>94 (2.3)</td>
<td>102 (2.5)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

[^1]: Data for treatment-emergent adverse events (TEAEs) were collected using the Medical Dictionary for Regulatory Activities (MedDRA) Version 20.1.[^2]: Events were considered serious if they were life-threatening or resulted in death, hospitalization, persistent or significant disability or incapacity, or medical or surgical intervention to prevent permanent impairment or disability.

  - Peripheral edema (6.5% VASEPA patients versus 5.0% placebo patients)
    - There was no significant difference in the prespecified adjudicated tertiary endpoint of new congestive heart failure, which occurred in 4.1% of VASEPA patients versus 4.3% of placebo patients.
    - Constipation (5.4% VASEPA patients versus 3.6% placebo patients)
    - Atrial fibrillation (5.3% VASEPA patients versus 3.9% placebo patients)
  - This adverse event finding is consistent with an increase in the prespecified adjudicated tertiary endpoint of atrial fibrillation or flutter requiring hospitalization, which occurred in 3.1% of VASEPA patients versus 2.1% of placebo patients (p=0.004).
  - The rate of treatment-emergent serious adverse events for bleeding was 2.7% in the VASEPA group versus 2.1% in the placebo group, with a nonsignificant, but trending p-value of 0.06.
  - There were:
    - No fatal bleeding events in either group.
    - No significant increases in adjudicated hemorrhagic stroke (0.3% in VASEPA patients versus 0.2% in placebo patients; p=0.55).
    - No significant serious central nervous system bleeding (0.3% versus 0.2%; p=0.42).
    - No significant gastrointestinal bleeding (1.5% versus 1.1%; p=0.15).

**Mineral oil placebo consideration and analysis**

In REDUCE-IT, a placebo containing mineral oil was used to mimic the color and consistency of the drug studied. No strong evidence for biological activity of the same mineral oil was identified in connection with FDA approval of VASEPA 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 VASEPA over placebo.

Each of the three VASEPA 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 for VASCEPA and 102.2% [9.0 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 mean absorption in some patients, this might contribute to differences in outcomes between the groups. However, the relatively small differences in LDL-C levels between groups would not be likely to explain the 25% risk reduction observed with VASCEPA, and a post hoc analysis suggested a similar lower risk regardless of whether there was an increase in LDL-C level among the patients in the placebo group. Although open label, Japan EPA Lipid Intervention Study (JELIS) previously demonstrated a 19% risk reduction without a mineral oil placebo.

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

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

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

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

- The REDUCE-IT steering committee, consisting of academic physicians, and Amarin representatives developed the protocol (Bhatt DL, Steg PG, Miller M, et al. N Engl J Med. 2018.) and were responsible for the conduct and oversight of the study, and data interpretation.

- The primary, secondary, and tertiary adjudicated endpoint analyses were validated by the data monitoring committee independent statistician.

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

- Further detailed data assessment by Amarin and regulatory authorities will continue and take several months to complete and record

- The final evaluation of the totality of the efficacy and safety data from REDUCE-IT may include some or all of the following, as well as other considerations:
  - New information affecting the degree of treatment benefit on studied endpoints
  - Study conduct and data robustness, quality, integrity and consistency
  - Additional safety data considerations and risk/benefit considerations
  - Consideration of REDUCE-IT results in the context of other clinical studies

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

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

- In REDUCE-IT, cardiovascular benefits appeared similar across baseline levels of triglycerides (less than 150 mg/dL, 150 to 199 mg/dL, and 200 mg/dL or greater).

  - Additionally, the reduction in major adverse cardiovascular events with VASCEPA appeared to occur irrespective of an achieved triglyceride level above or below 150 mg/dL at one year, suggesting that the cardiovascular risk reduction was not tied to achieving a 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 (IACCORD Lipid, AIM-HIGH, and HP52-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).

VASCEPA® (icosapent ethyl) Capsules, for oral use

Brief summary of Prescribing Information

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

1 INDICATIONS AND USAGE

VASCEPA® (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet and exercise regimen before receiving VASCEPA and should continue this diet and exercise regimen with VASCEPA.

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

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

2 DOSAGE AND ADMINISTRATION

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

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

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

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

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Monitoring: Laboratory Tests

In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy with VASCEPA.

5.2 Fish Allergy

VASCEPA contains ethyl 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 VASCEPA; VASCEPA should be used with caution in patients with known hypersensitivity to fish and/or shellfish.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

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

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

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=309)</th>
<th>VASCEPA (N=622)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthralgia</td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>2.3</td>
</tr>
</tbody>
</table>

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

An additional adverse reaction from clinical studies was ophthalmo给力 pain.

7 DRUG INTERACTIONS

7.1 Anticoagulants

Some published studies with omega-3 fatty acids have demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in those studies has not exceeded normal limits and did not produce clinically significant bleeding episodes. Patients receiving anticoagulants with VASCEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

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

In a multigenerational developmental study in pregnant rats given oral gavage doses of 0.3, 1, 3 g/kg/day ethyl-EPA from gestation day 7-17, an increased incidence of absent optic nerves and unilateral testes atrophy were observed at >3.0 g/kg/day at human systemic exposure following an oral dose of 4 g/day based on body surface area comparisons across species. Additional variations consisting of early incisor eruption and increased percent cervical ribs were observed at the same exposures. Pups from high dose treated dams exhibited decreased copulation rates, delayed estrus, decreased implantsations and decreased surviving fetuses (F2) suggesting multigenerational effects of ethyl-EPA at 7 times human systemic exposure following 4 g/day dose based on body surface area comparisons across species.

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

In pregnant rats given ethyl-EPA from gestation day 17 through lactation day 20 at 0.3, 1, 3 g/kg/day complete litter loss was observed in 2/23 litters at the low dose and 1/23 mid-dose dams by 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 VASCEPA is administered to a nursing mother. An animal study in lactating rats given oral gavage 100 mg/kg ethyl-EPA demonstrated that drug levels were 6 to 14 times higher in milk than in plasma.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Of the total number of subjects in clinical studies of VASCEPA, 33% were 65 years of age and over. 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

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

10 NONCLINICAL TOXICOLOGY

10.1 Carcinogenicity, Mutagenesis, Impairment of Fertility

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

In a 6-month carcinogenicity study in Tg.rasH2 transgenic mice with oral gavage doses of 0.5, 1, 2, and 4.6 g/kg/day icosapent ethyl, drug-related incidences of benign squamous cell papilloma in the skin and subcutis of the tail was observed in high dose male mice. The papillomas were considered to develop secondary to chronic irritation of the proximal tail associated with fencal 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 vivo mouse micronucleus assay. A chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells was positive for clastogenicity without metabolic activation.

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

17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

See VASCEPA Full Package Insert for Patient Counseling Information

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Five New Care Models For Pharmacy

Employers, the federal government, and patients are not happy with the way healthcare is delivered and financed. Hospitals, physicians, and pharmacies try to remain relevant as new technologies are developed to commoditize healthcare services and enable patients to become true consumers.

Pharmaceutical companies continue to improve healthcare with new therapeutic agents. The value of these new drugs can benefit society, but even more so, their impact on healthcare economics is staggering. Specialty drugs to treat certain patients present new challenges for health plans and pharmacy benefit managers (PBMs).

As pharmaceuticals grow to consume 30% of the healthcare dollar, traditional care models need to change in order to deliver the best healthcare outcomes and real value or they will become obsolete.

Currently, drugs covered under the pharmacy benefit are distributed through community, mail order, and specialty pharmacies. PBMs utilize proven systems — for example, online drug claims processing, pharmacy network contracting, and drug rebates — to manage unit drug cost.

In the future, drugs covered under the medical benefit, many of which are specialty drugs, will need new systems and processes to manage these drugs administered through the physician's office, home infusion, and hospitals.

This creates a need for new care models.

Current Care Models
The five current care models in pharmacy are: community, hospital, long-term care, mail order, and specialty.

These models are facility-driven by site of care, healthcare professional driven, expensive, and inefficient.

The key shortcomings of the current care models are that they:

- Do not use a population-health approach to identify the patients to treat
- Make the patient come to the site of care (hospital, pharmacy, or physician office)
- Dispense pharmaceuticals with a "one-size-fits-all" approach that creates waste
- Make minimal use of information technology
- Require each facility work in its own silo with no integration of overall patient care activities

New Care Models
New care models in pharmacy are being created that are patient driven, leverage technology, and improve accessibility. These five new care models are: dispensing kiosks, multidose strip packaging, patient-centered home, precision medicine, and telehealth.

The key benefits of these new care models are that they do one or more of the following:

- Use data analytics to identify patients who would benefit the most from these new services,
- Deploy pharmacists into the patient’s home to provide high-touch care
- Dispense pharmaceuticals in the most effective way to minimize waste
- Leverage information technology
- Integrate pharmacy with overall patient care activities

Amazon will disrupt the community pharmacy industry. This will give employers and the federal government new choices in how healthcare is delivered. However, they will need a digital health strategy to leverage these new services to make sure the sickest patients can be treated in the patient care setting that can deliver measurable improvement on health outcomes. The result will be new benefit designs and ways to finance care.
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MARCH 2019

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To learn more about our family of kits or specific product information, visit www.cutispharma.com or call us at 1-800-461-7449, ext 119.
Walgreens Tests Pharmacy-Only Stores

Walgreens’ latest move is reminiscent of corner neighborhood pharmacies. The chain is testing very small stores that are only a pharmacy with a small front-end section.

“The stores will offer a full pharmacy and limited front-end offering, which would include FedEx and also ship-to-store services,” Walgreens Spokesperson Jim Cohn tells Drug Topics. Some over-the-counter products might be included in the front end as well, Cohn says.

The small-format stores are being tested in a handful of locations; Cohn declined to give further details on the test sites. GoUpstate.com reported that the first store is opening in Boiling Springs, SC, in an area where a nearby Rite Aid store recently closed. “The new Walgreens will focus on filling prescriptions and will not have an attached grocery,” Andy Hayes with Spencer/ Hines Properties, which leased the 2,000-square-feet space in a shopping center to Walgreens, says.

The small format is not that far of a departure from the on-site pharmacies that Walgreens manages in health systems and at corporate clinics, Ash Shehata, principal at KPMG and partner of the firm’s Global Healthcare Center of Excellence, tells Drug Topics. “Walgreens has traditionally been one of the more savvy real-estate investors in the retail sector when it comes to picking locations. Also, the merchandising dynamics are changing with pharmacy sales driving most of the growth and consumable sales not [driving growth],” he says.

In certain markets, it may make sense for Walgreens to offer a pharmacy-only location. “Sales per square foot could make these locations extremely productive for Walgreens. Retailing is one of the most competitive segments of the U.S. economy, and it makes sense to play to one’s strengths, such as Walgreens and its peers focusing on pharmacy and health,” Shehata adds.

CVS’ HealthHUBs concept stores focus on goods such as sleep apnea masks and services that help customers manage chronic conditions. Meanwhile, Walgreens’ newer health-centric stores offer hearing and eye services along with point-of-care lab tests.

“Most retail pharmacies are looking to increase their capabilities to better engage their customers, whether that’s through home delivery services, opening urgent care centers, or focusing on wellness. So, it is not clear that other pharmacies are looking to go to a 2,000-square-foot footprint, but many are willing to reduce general merchandise and shift to health and wellness products,” Shehata says.
NEW GUIDELINES: Pharmacists Should Be Vaccine Advocates

APhA’s revised immunization guidelines urge pharmacists to protect their patients’ health by being vaccine advocates and to report adverse events, among other recommendations.

As the pharmacist’s role in raising the rate of immunizations continues to expand, APhA revised its Guidelines for Pharmacy-based Immunization Advocacy and Administration. The guidelines cover five areas: prevention, partnership, quality, documentation, and empowerment.

The updated recommendations say pharmacists should document immunizations fully, report clinically significant events using the Vaccine Adverse Event Reporting System (VAERS), educate patients about immunizations, and respect patients’ rights, as well as their beliefs.

They also call for pharmacists to collaborate, coordinate, and communicate with immunization stakeholders to protect the community from vaccine-preventable diseases.

Pharmacists should ensure quality by achieving and maintaining competence to administer immunizations, according to the guidelines.

Originally approved in 1997, the APhA Board of Trustees reviewed, updated, and approved the guidelines in 2012 and again in late January 2019.

---

Burnout Common in Critical Care Pharmacy

A high rate of critical care pharmacists suffer from burnout syndrome, a recent survey says. The nationwide survey, presented at ASHP’s 2018 Midyear Clinical Meeting, found that 64% of respondents met the criteria for a high degree of burnout.

Why the burnout in pharmacy? “There’s a lot of quick decision making that needs to be done. There’s a lot of life and death. There are often these high periods of go-go-go intensity where you don’t have time to stop, you don’t have time to take a break, to eat, to do anything because patients need you,” says Amanda M. Ball, PharmD, clinical manager of Clinical and Patient Care Services at Duke University Hospital in Durham, NC.

Based on her previous research, Ball tells Drug Topics that clinical care pharmacists who have been on the job for five years or less have a higher rate of burnout, defined by the National Academy of Medicine (NAM) as a syndrome with “a high degree of emotional exhaustion, depersonalization, and a low sense of personal accomplishment at work.” Critical care pharmacists who have been on the job for five years or less have a higher rate of burnout, the researchers find. However, they have not identified a reason for the early burnout, Ball says.

Doctors Misprescribing Fentanyl

Many patients who were prescribed fentanyl should not have received it at all, a new study says.

The study, published in the Feb. 19 JAMA, was based on documents obtained via public records requests. Researchers set out to determine whether the FDA’s transmucosal immediate-release fentanyl (TIRF) risk evaluation and mitigation strategy (REMS) program met its goal of preventing inappropriate use of TIRF products.

They found that, after 60 months, between 34.6% and 55.4% of patients prescribed TIRF were opioid-intolerant.

“Over the 60-month period examined, there were few substantive changes made to the REMS to address evidence of high rates of off-label TIRF use, and, although the REMS program had a noncompliance plan, there was no report of prescribers being disenrolled for inappropriate prescribing,” the researchers wrote.

In related news, the FDA is looking for evidence-based ways to fight opioid addiction by reducing the flow of prescription opioid products into patients’ homes, according to ASHP.

The FDA asked a National Academies committee to develop a framework for evaluating existing clinical practice guidelines on the prescribing of opioids to treat acute pain resulting from specific conditions or medical procedures. The committee will also identify acute pain conditions for which opioid prescribing guidelines are needed and outline a future research agenda for opioid use in acute pain.

Generic Opioid Addiction Drugs Cleared

The U.S. Supreme Court ruled that generic drug manufacturers could make generic versions of Suboxone (buprenorphine and naloxone), the blockbuster opioid addiction treatment.

Immediately after the ruling, Indivior Plc, which manufactures Suboxone, launched a generic version of the drug.

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Small doses

Revenues, Gross Profit Dip to Lowest Levels Since Medicare Part D, Great Recession

The 2018 NCPA Digest revealed that 92% of revenue for independents comes from prescription drugs, but margins are hampered by low reimbursement rates.

The 10-year trends show that, since the Medicare Part D prescription drug benefit was introduced, pharmacists’ gross margins have declined steadily. In 2017, 36% of prescriptions in independents were covered by Medicare Part D, and 17% by Medicaid; more than half of independent volumes are now paid by a government program. Most of the Affordable Care Act came into effect during this time as well.

Pharmacists have cut payroll to help fill in the lost revenue, but it isn’t enough.

TABLE 1

<table>
<thead>
<tr>
<th>Year</th>
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TABLE 2

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<td>2008</td>
<td>Sales 100%</td>
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<tr>
<td>2009</td>
<td>Cost of Goods Sold 76.8%</td>
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<tr>
<td>2010</td>
<td>Gross Profit 23.2%</td>
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<td>2011</td>
<td>Payroll Expenses 13.5%</td>
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<td>2016</td>
<td></td>
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<tr>
<td>2017</td>
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Drug Spending Soared 18% in 2018

On average, drug spending climbed 18% in 2018, according to a new report.

Commercial per-member-per-month (PMPM) medical drug spend increased to $29.97, which is above the 14% average annual trend over the last five years, according to Magellan Rx Management, the PBM division of Magellan Health, in its annual Medical Pharmacy Trend Report.

Similarly, Medicare PMPM saw its largest spike of 12% to $52.19, far exceeding the average annual trend of 5%. Magellan attributes the rise to increases in PMPM spend and the use of immuno-oncology agents and other new pharmaceuticals.

Oncology had the highest PMPM spend across all lines of business. Rituxan (rituximab), Herceptin (trastuzumab) and Avastin (bevacizumab) remained in the top five drugs for commercial plans. By 2022, chimeric antigen receptor T-cell therapies (CAR-T) for oncology immunotherapy treatment are projected to have an increase in PMPM spend of 581%, according to Magellan Rx Management.

“The data shows that the trend over the last five years for medical pharmacy drugs was 68%, representing the largest growth over the last nine years, reinforcing the need for effective management strategies in medications billed through the medical benefit,” Magellan Senior VP Kristen Reimers, RPh, said in a statement.

Acid Reflux Drugs Linked to Kidney Disease Risk

People taking protein pump inhibitors (PPIs) such as omeprazole (Prilosec), esomeprazole (Nexium) and lansoprazole (Prevacid) have a higher risk of developing kidney disease, a new study says.

Published in the Feb. 19 issue of “Scientific Reports,” the examination of the FDA Adverse Effect Reporting System (FAERS) database for unexpected consequences of PPI consumption was led by researchers from the Skaggs School of Pharmacy and Pharmaceutical Sciences at the University of California San Diego.

Patients who took only PPIs were 28.4 times more likely to report chronic kidney disease and 35.5 times more likely to report end-stage renal disease than those taking histamine-2 receptor antagonists such as famotidine (Pepcid) and ranitidine (Zantac), the researchers found.

Patients who took only PPIs reported a kidney-related adverse reaction at a frequency of 5.6%, compared to 0.7% for patients who took only histamine-2 receptor antagonists.
Black patients with atrial fibrillation are significantly less likely to receive oral anticoagulants than white and Hispanic patients, a study has found.

In addition, the quality of the anticoagulants prescribed was lower in black and Hispanic individuals, according to the study, published in the December 2018 issue of *JAMA Cardiology*.

“For patients with atrial fibrillation, long-term oral anticoagulant use can reduce their risk of stroke. Even after our analysis adjusted for socioeconomic factors, black patients were still less likely to receive these types of drugs,” says Utibe R. Essien, MD, MPH, lead author and assistant professor in the Division of General Internal Medicine at the University of Pittsburgh, in a statement from the university.

Reasons for the racial disparities among anticoagulant use can include limited access to specialists, out-of-pocket costs, medication adherence, and implicit bias, according to the article.

“Blacks with atrial fibrillation are already at a higher risk of complications, so improving health literacy and reducing disparities related to medication use could help improve their overall quality of care and reduce complications,” Essien adds.

There was no significant difference in the use of oral anticoagulants between white and Hispanic patients. But after controlling for clinical and sociodemographic factors, black patients had 25% lower odds of receiving any oral anticoagulant drugs, compared with white and Hispanic patients. They also had 37% lower odds of receiving any of the newer direct-acting oral anticoagulants (DOACs), which are considered to be safer choices for anticoagulation, according to the statement.

The study also found that black patients (15.5%) and Hispanic patients (18.1%) treated with DOACs were more likely to receive inappropriate dosing than were white patients (12.6%).

Among patients receiving Warfarin (coumadin), the median time in therapeutic range was lower in black patients (57.1%) and Hispanic patients (51.7%) than in white patients (67.1%).

Racial Disparities in Oral Anticoagulant Prescription Patterns

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The Murky Waters of ‘White Coat’ Marketing

Last year, the pharmaceutical industry faced a slew of lawsuits in federal courts, all with remarkably similar allegations. These complaints alleged that a large number of drug makers used improper “white coat” marketing techniques to sell drugs. The complaints alleged that large companies hired nurses and physicians to hawk their products, thereby confusing unwitting patients.

The lawsuits alleged that the companies had made billions of dollars through these allegedly inappropriate practices. These lawsuits are still unfolding in federal courts.

Given the high stakes that companies face with these claims, drug manufacturers would be well served by understanding the rules governing marketing of pharmaceutical products. We outline the basic legal framework and offer some practical advice to avoid allegations of wrongdoing.

Why Its A Slippery Slope

White coat marketing refers to the practice of physicians, nurses, pharmacists and other professionals advertising or marketing pharmaceutical products. To be clear, using healthcare professionals to market or advertise products is not unlawful or illegal; however, the government has historically viewed white coat marketing more cautiously because healthcare professionals are in a position of public trust, and may exert influence when recommending healthcare-related items or services. The government has argued that patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

The government has also raised concerns not just when practitioners directly market products to patients, but also where these professionals act as consultants, advisors, or researchers in connection with marketing and research activities. The government often casts a skeptical eye on arrangements where drug manufacturers engage physicians to perform research, data collection, and consulting services, serve on advisory boards, or speak at meetings.

Practical Advice

The government is skeptical about these arrangements; practitioners, and drug manufacturers alike would benefit from taking a cautious approach. Here are a few common-sense suggestions:

- When healthcare practitioners advertise or market pharmaceutical products, be sure the information being conveyed to patients is accurate and not deceptive. If the information is found to be objective and accurate, the government has historically taken less interest in prosecutions.
- Where possible, have healthcare practitioners advertise in a passive rather than active manner. The government has blessed arrangements, for example, where practitioners laud products on a website, finding that ads on websites are generally more passive and less intrusive to patients. The government is more likely scrutinize those who directly advertise to their own patients.
- Practitioners who advertise certain products should not have a direct relationship with the patients to whom they advertise. The government has historically been concerned with patients being misled about objective health information. A way to insulate yourself from this concern is to separate practitioners who market products from those with direct patient-physician relationships.

These tips will not prevent all potential questions from regulators. But, “an ounce of prevention is worth a pound of cure.” Nowhere is this truer than in modern healthcare.
McKesson’s Jhaveri Talks about Health Mart Pharmacies

By Valerie DeBenedette, managing editor

Nimesh S. Jhaveri, MBA, RPh, became president of Health Mart Pharmacies and senior vice president at McKesson Corporation in November. Previously, he had been with Walgreens as vice president of healthcare services.

Health Mart is McKesson’s nation-wide network of independently owned pharmacies.

**DT:** At Health Mart, what do you do for independent pharmacies?

**NJ:** What I do and what Health Mart does for independent pharmacies is, one, provide support so they can stay competitive in the marketplace; two, provide a personalization of their business model so they can provide more services that are relevant to their patients; three, support them through our distribution channel, our contracting for third-party payers, and any other tools that we provide them to really keep their business strong, competitive, and relevant for their patients.

All of the tools, contracting, distribution, everything that a pharmacy owner and a pharmacist needs to make that pharmacy tick is being done in the background. That’s the way you want to look at it, so if that pharmacist needs help they would call us and we will provide them with tools. If they need help in their contracting with a health plan or PBM, we would provide that. If they need help with securing a certain medication for their patient, we will provide that. So really, it’s all of those back end services that make a pharmacy run.

We have several different services and tools. One is a field team that supports our independents one on one. Our franchise directors are in the field. They’re working hand-in-hand with our owners on various questions from how to manage their P&L to how to manage their clinical services or their front end. So we have boots on the ground.

We also do education sessions, what we call town halls. In those town halls, we will teach them everything from how to run their business better to how to do clinical services better.

At the end of the day we want this to be a seamless operation, so a pharmacy owner and a pharmacist doesn’t have to worry about all of that. Let us do the worrying.

We want to make sure that you are doing what you do best, which is being a great pharmacist, taking care of your patients, focusing on the clinical activities, focusing on medications therapy, and focusing ultimately on how to drive better outcomes. And at a better cost. You know, that’s what a pharmacist is trained to do. So let us do everything else in the background.

**DT:** How large is the Health Mart network. How does that affect its franchisees?

**NJ:** We just crossed the 5,000 store barrier. It’s a big milestone. Everybody knows Walgreens. That was my previous employer for 29 years. And everybody knows CVS. Health Mart is No. 3 now. And I think that’s a huge milestone for Health Mart and for independents.

With scale comes the ability to do other things and the ability to drive better outcomes and services and things of that nature, certainly for the patients. It also allows us to negotiate better on their behalf.

The biggest difference between a national chain drugstore and a Health Mart is the ownership of that pharmacy. That...
pharmacy is owned and operated by an independent owner, who is more than likely the pharmacist. There's a vested interest for them to drive that business in the most effective way possible, individually, store by store.

Another big difference that I see is that most of these owners are generational. They have been taking care of those patients, maybe their moms and dads, and maybe even their moms and dads. So there's the relationship, a long-term seated partnership with their patients that in many instances a large chain may not have. And how do you take advantage of those relationships? How do you take advantage of that trust that the patient has with that pharmacist because there has been a relationship over the years?

I think that's the biggest difference. That's why I'm extremely bullish, and extremely optimistic on what independents can do in the pharmacy space, because of that trust and relationship.

Let's be honest here. At the end of the day in healthcare, there's nothing more important than trust and relationship to drive better outcomes.

DT: Coming over from Walgreens, did you have to do any shift in your thinking, from being an executive with a big chain to working with a large group of independent pharmacies?

NJ: The shift in my thinking is more from the side of how do we keep owners viable and competitive, because they don't have the power of a Walgreens infrastructure or a CVS infrastructure. But they do have the power of a McKesson and a Health Mart infrastructure, which is what we're trying to help them take advantage of.

At the end of the day, all of us are striving to do one thing, which is to elevate the role of pharmacists so they can practice at the top of their license. Whether you're in a chain, or grocery, or an independent, or hospital setting, we should all be working towards one goal, which is to help pharmacists practice at the top of their license, provide the best care that they can and then ultimately be remunerated for those services, whether it's through the payer, or through the government or whatever the case is, and hopefully we'll get that through things like provider status.

DT: You've received several patents for pharmacy-related technology in your career. If you were still creating technology for pharmacies, what would you want to be working on next?

NJ: I'm inspired by technology based on artificial intelligence, biosensors, and digital technology that allows a frictionless experience for patients while capturing critical information to help improve overall health and change behavior, and virtual reality to help patients manage their conditions such as pain during an immunization in a more effective manner.

I'm also intrigued by clinical-based technology like immunootherapy for unique cancer treatments and liquid biopsy to help our fight with monitoring cancer cells. With this technology, you may be able to monitor cancer cells through a blood test and in a noninvasive way at the pharmacy.

### A Checklist for Starting a Pharmacy

Starting a pharmacy can happen in 6 months to 9 months if you're properly prepared. Here are some ways to get your doors open on schedule:

1. **Assemble a team of advisors.** This includes mentors, legal counsel, and professional resources like accountants and insurance agents.
2. **Find the right location.** Can your chosen location sustain another pharmacy? Are there other independent pharmacies nearby? What about healthcare businesses or offices that can help drive traffic to your pharmacy?
3. **Create a business plan.** A business plan will help guide you in the process of setting up a pharmacy and will help you secure financing.
4. **Select your financing options.** Lenders will be looking for an initial upfront investment from the potential owner, a good credit score, and sufficient working capital.
5. **Do a test run.** This is where you test out your set up and work flow routines, organize the layout and inventory, announce your new business, plan events, and get involved in the community.

Source: McKesson
Vaccination Guide

Boost Revenue, Clients With Vaccination Services

START UP AND SET UP P17

TRAVEL CLINIC TIPS P19

MARKETING & COMPETITION P21
Your digital dispensary is on Twitter! Follow us for the latest news, views, and insights for your business and the profession.

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Offering more than just the flu shot and becoming a full-service vaccination clinic is one way pharmacies can distinguish themselves from other pharmacies, bolster revenue, and become a true healthcare destination for their patients.

John Beckner, RPh, senior director of strategic initiatives for NCPA, defines a full-service vaccination clinic as a pharmacy that is willing to offer all the vaccinations approved by the American Council on Immunization Practices (ACIP).

"Full-service can vary by states because states have different laws and regulations particularly when it comes to age," Beckner says.

While offering a full-service vaccination clinic can help a pharmacy stay competitive and generate additional revenue, setting one up requires forethought, planning, and strategic implementation to be successful.

"The gateway and the entry is flu, and really the sky is limit from there in how you expand it and turn your pharmacy into a healthcare destination," says Lisa Petersen, vaccine program manager for McKesson Pharmaceutical Solutions and Services.

**Why Have a Clinic?**

Offering a full-service vaccination clinic can have significant advantages for the public as well as the pharmacy itself.

Petersen says pharmacies can earn approximately $38,000 in additional gross profit by offering vaccines. Expanding the offerings beyond the flu vaccine also further demonstrates the pharmacist’s ability to be a trusted and reliable member of the healthcare team, while also offering the customer a level of convenience and accessibility not available in other healthcare settings.

"It's a tremendous upside opportunity and a modest downside opportunity," says Bruce Kneeland, an independent community pharmacy consultant.

According to Beckner, a full-service vaccination service has the potential to also drive your prescription business. "It helps brand your pharmacy as a wellness destination, it helps drive your prescription volume and really it’s an opportunity to help you promote other patient care services that you might be offering such as health screenings or point of care testing," he says.

**Determining State Regulations**

The first step in establishing a vaccination clinic is researching what pharmacies are allowed to do within each state. "As a pharmacy is setting up a full-service vaccination service or immunization service, one of the first things they need to do is be knowledgeable and aware of the different laws and regulations in their particular state," Beckner says.

Pharmacists can discover this information through their own research, using the NCPA website, contacting their state’s pharmacy association, or calling their state board of pharmacy.

Some states will be regulated by immunization collaborative practice agreements (CPA), or legal documents that are state specific. These agreements, must be signed by a physician and outline all...
the vaccinations a pharmacist is allowed to give in their pharmacy.

"You want to read your CPA. What does it say? Can you vaccinate anyone that's under 18 years of age in that state? Can you vaccinate babies?" Petersen says. "That's when you really have to fine line read the regulations. You need to have the emergency plans, you need to look at the state regulatory reports, the consent forms, and make sure you have all of that."

Pharmacies in states with CPA requirements will either need to identify a physician to partner with on their own or work with a company like McKesson, which offers a program that identifies the appropriate legal documents for a state and finds a physician to sign off on the agreement doing much of the "heavy lifting" for the pharmacy, Petersen says.

**Assessing Your Pharmacy**

Once pharmacies have taken a state-level review of the restrictions and opportunities within their own state, they need to turn their focus much closer to home: their own pharmacy.

Before implementing a full-service plan, pharmacists need to assess the skill level of their staff, the pharmacy’s ability to handle an increased workload, and the storage requirements that will be necessary for the list of vaccines they want to administer.

Pharmacies will also need to consider their store set-up. The best-case scenario would be that the pharmacy would have a private area where the shots could be given to provide patients with the privacy they need.

"Ideally, you’ve got a private wellness center type room to be able to provide this service, that would be an ideal situation, but not every pharmacy is going to have a nice office type layout," Beckner says. "So you are going to need to be flexible in terms of where you are going to offer the flu shot."

Aside from the physical space to administer the vaccines, pharmacies also need to make sure they have an emergency kit on hand, with epinephrine, a sharps disposal, alcohol wipes and other items that make administering the vaccine a smoother and more professional process for the both the pharmacist and patient.

**The Billing Process**

A key to a successful vaccination clinic is having the billing process set up before advertising it. Pharmacies can research the billing requirements and implement their own programs.

However, there are third-party vendors, including OmniSYS, TransactRX and electronic billing services, that are designed specifically to assist pharmacies in billing for vaccinations, Petersen says.

“That’s their wheelhouse. They are subject-matter experts. They partner with the pharmacist, and the pharmacist pays them directly to process their claims," she says. "That way they make sure they are checking the right boxes, they are coding the right things, they are making sure they are putting the right pertinent information to where they get reimbursed for not only the vaccine but for the administration cost, so that all of that is accounted for.”

**Inventory**

Chris J. Meyer, PharmD, a pharmacist at Medicap Pharmacy in Austin, MN, says pharmacies face greater inventory challenges now because many manufacturers have gone from allowing pharmacies to buy vaccines in single quantities to often requiring they be purchased in bulk packages.

This may add additional storage and investment considerations for pharmacies, but Meyer believes pharmacies who want to be able to compete need to have the vaccines in stock.

“You have got to have product here if you are going to run a business, and if you don’t, they are going to go elsewhere," he says.

It can be particularly difficult for pharmacies in their first year of offering immunizations or adding a particular vaccine because there is no past history to predict how much to order. Beckner suggests pharmacies talk with other pharmacies in the area that have offered similar vaccines to see whether they are willing to share their experience. "Some of these vaccines are pretty expensive, so inventory is definitely a consideration," he says. "I think you try to gauge the demand."

Creating a full-service vaccination clinic can also be an effective strategy to retain customers and maintain other more common vaccination business, such as flu shots.

"If they come to your pharmacy and you're not offering a particular vaccine, you don't want to be referring to another pharmacy, so you really want to be able to offer the full-service," Beckner says.

Petersen agreed that pharmacies really need to begin thinking of their vaccination programs as offerings that are available 365 days a year and that extend beyond the traditional flu vaccines. Targeting college students about to head off to school, for example, helps signal to customers that the pharmacy is a one-stop shop for all a customer’s vaccination needs.

Offering a full-service vaccination clinic can have its challenges, but pharmacy owners don’t have to go at it alone. There are software and programs specifically designed to help ease the process for pharmacies. For example, McKesson offers a VaccineComplete program that alerts pharmacists to patients in their store who might be missing necessary vaccinations. They also offer a Vaccine Starter Kit that includes six months of customer-service support and a program for Health Mart pharmacies to secure CPAs. ■
When preparing for a trip, travelers may want to check out advice on how to make that trip a healthier one. One way to do so is to visit a travel health clinic at a pharmacy.

Research suggests that more than half of all travelers experience health problems while on a trip, many of which could be prevented by vaccinations or bringing along appropriate medications. Getting sound medical advice before departure can minimize the chance of any health complications while traveling, whether that advice includes a tetanus booster, a yellow fever vaccination, or stocking up on mosquito repellent.

At a travel health clinic, visitors can meet with a pharmacist to compose a customized travel plan that factors in their personal health history. Travel clinics not only offer vaccinations for diseases that are more prevalent at some destinations, but can also suggest medications to bring to combat common travel-related problems such as altitude sickness or digestive upsets. Using dedicated pharmacy software and online resources, pharmacists can offer destination-specific suggestions. Yet, many travelers may not know that travel health clinics exist or that there is one in a nearby pharmacy.

“It is something often overlooked by travelers; travel agencies rarely mention it, and few medical practices provide it,” says Jeffrey Goad, PharmD, a professor in the department of pharmacy practice, School of Pharmacy at Chapman University in California. “So, the pharmacy is an excellent place to get your medications, vaccinations, OTCs, and supplies for travel all in one place.”

Pharmacy travel health clinics are very convenient and can be a source of revenue for pharmacies, but only if travelers know they exist. That’s why marketing is important.

Marketing Your Service

Publicizing travel health clinic services need not be complicated or expensive. Marketing efforts can be as simple as posting a notice or a travel readiness checklist in the pharmacy or including clinic information on a phone message or on the pharmacy website.

“In store advertising has been reported by pharmacies to be the most successful," says Goad.

At Sand Run Pharmacy in Akron, OH, Tom Lamb, RPh, uses a large television billboard to inform his customers of the pharmacy’s services, including what’s available at its new travel clinic.

“It’s easy to assume everyone knows what we offer, but they may not know,” Lamb says.

After years of giving flu and pneumonia vaccinations, Sand Run began offering travel vaccinations in 2018. Based on the community’s enthusiastic response, Lamb decided to open a travel health clinic this month. To attract customers, who might not necessarily visit the pharmacy for a flu shot, they actively sought referrals, contacting the local health department, physicians, and travel agents.

Local health departments that used to handle travel vaccinations are not doing as much as they once did, says Lamb. “They are not keeping vaccines available, so they look to refer to other sources in town.”

Successfully marketing a travel health clinic involves identifying target audiences, whether that’s a nearby college with students who might travel for an exchange program, a church that is planning a group mission trip, or businesses that regularly send employees abroad. Contacting these sources and letting them know what the clinic offers can lead to referrals.

How to market a travel health clinic:
- Contact local health departments
- Contact area physicians
- Contact nearby schools and businesses
- Contact nearby travel agencies
- Advertise your services in the pharmacy
- Advertise your services via social media
- Offer to speak about what you do at businesses, organizations, and schools

By Joan Vos MacDonald, contributing writer

Consultations can extend sales, services beyond immunizations

Rise In Global Travel Fuels Business Opportunities

VACCINATION GUIDE
Getting Referrals

Travel agents have been a very good source of referrals for the pharmacy, especially when it comes to group trips. A travel agency might be working with 20 or more people who are going on the same safari, and each traveler might need vaccinations and recommendations.

“In a group of 20 or more people going on one safari, one prescription can lead to 20 prescriptions for the other people who also need it,” Lamb says. “One planning-ahead type person doing the research on needed vaccines leads to 20 more getting vaccinations. Word of mouth is great. I recently also had another group, a church group going on a mission trip. If you get one person in the group, you get a lot more.”

According to Lamb, these marketing efforts have contributed to the clinic’s early success.

“People are looking for a source that is easy to work with, that is responsive to their needs, that has a quick turnaround time, basically, that makes it easy for them. That’s what our goal is.”

Contacting physicians about their travel health clinic services has also been a very successful marketing tool for Bremo Pharmacy in Richmond, VA, perhaps their most successful.

The pharmacy set up its travel clinic more than six years ago and one of their first outreach efforts was to send a mass fax to all the pediatricians and primary care doctors in the area, explaining that the clinic gave vaccinations and consultations.

“We told them this is what we offer and that we’re a good resource” said Jennifer Helmke, PharmD. “As a result we developed a good relationship with a lot of physicians. Many don’t necessarily want to do vaccinations and they need someone to refer patients to.”

The department of health was also a good source of referrals for Bremo. “Patients can go to the department of health for vaccinations, but a lot of times people go there and they are booked six months out, so people who go there for a consult may get referred to us.”

Helmke speaks about travel health outside the clinic at least once a year. “I’m often asked to provide a travel topic to discuss at a nursing home, in an assisted living facility or to the elderly at a community center,” she says. “That brings in a lot of people at once.”

Besides online marketing, listing services on Facebook and its website, the pharmacy also obtains referrals from travel agents. “Travel agents are limited in that they know customers are going somewhere they should get a vaccination, and that they should probably speak to someone. They are aware of what their customers need, but not always of where to send them,” she says.

Individualized Advice

Helmke decided to set up the travel clinic because she was passionate about travel, so when patients do come in for a consultation she wants it to be comprehensive. “We ask patients where they’re going, what type of activity they plan on doing that might put them at an increased health risk, so we can evaluate,” said Helmke. “There’s a difference between a 25-year-old going hiking versus a 40-year-old going on a cruise. There are different risks with each activity, age, and environment.”

She likes to share tips that may come in handy, some of which she used in her own travels. For example, preemptively spraying your clothes with some brands of inexpensive bug spray can provide an extra layer of protection when traveling somewhere known for disease-carrying insects. It’s simple, but a tip like that can make all the difference. “I want to be sure they go home with the full package,” she says.

There are many ways for travel health clinics to get the word out to those who might need their services. A good first step is always to assess the particular needs of your community and make contact with those who can help spread the message. For example, if there’s a school nearby, a student health services might be interested in promoting the service on campus.

Corporate human resource departments may also appreciate a resource for any travelers they sends overseas. Contacting the outreach coordinator at local health departments can help travel health clinics promote the services they provide.

Clinics can also join or subscribe to organizations or services that maintains listings of travel clinics on a high-volume website; such as Shoreland’s Travel Health Online, the International Society of Travel Medicine, the American Society of Tropical Medicine and Hygiene, and other travel medicine resources. Travel health clinics offer valuable services and an important part of any travel health clinic plan should be letting the community know what they offer.
More than 280,000 pharmacists have been trained to administer vaccinations, according to the American Pharmacy Association.

But as more pharmacists join their ranks, the competition among chains, and independent stores offering vaccination services also grows.

More patients than ever are turning to pharmacies for their vaccinations. In 2017, 28.2% of those who received the flu vaccine reported getting it at pharmacies or other retail stores, according to the CDC.

As more patients turn to pharmacies for their vaccination needs, pharmacies offering standard immunizations who want to remain competitive in the saturated market will need to employ new tactics and strategies to attract customers, while ensuring that operations remain efficient.

Targeted Marketing Campaigns

As the number of pharmacies offering immunization services increases, pharmacies will need to be more proactive in securing their business.

“Marketing is key. I mean you’ve got to market your service. Historically, pharmacies have not done a great job of marketing their nondispensing patient care services,” says John Beckner, RPh, senior director of strategic initiatives for NCPA.

“The pharmacy needs to let the medical community in their particular area know what they are doing because probably in most cases the physicians are not offering that service.”

Rather than waiting for business to walk through their door, pharmacy owners recommend trying to solicit business from targeted patient populations whether its assisted living centers, area employers, or church groups.

“As our market—our pharmacy market—got a little bit more competitive and the big box chains started to pick up and do this, then I started reaching out to businesses and local events to come in there to vaccinate their employees, or to be in certain areas where there were going to be big groups of people,” says Chris J. Meyer, PharmD, a pharmacist at Medicap Pharmacy in Austin, MN.

Establishing solid relationships with area employers can be one strategy to maintain business year after year. Meyer, who says his pharmacy peaked in 2009 administering close to 6,000 vaccinations that year alone, says many of the businesses he visits to provide vaccination services, either before or after normal operating hours, continue to call him each year.

Meyer also sent letters out to childcare centers, school nurses, and others in the community when his pharmacy began doing flu and strep tests to increase awareness about the full-range of services offered at the pharmacy.

Dennis Song, RPh, owner of Flower Mound Pharmacy in Flower Mound, TX, has been offering vaccines at his pharmacy for 21 years.

“We were very proactive from day one,” Song says.

The pharmacy began by offering off-site clinics for employers and community organizations Song already had an established relationship with, including his church, lawyer’s office, and accountant.

Over the years, the pharmacy has also partnered with cleaning companies, area school districts, or senior living homes to offer clinics for their employees.

“We had to get niches because when it was saturated and the Walgreens of the world, when they were giving flu shots in August and everybody was getting theirs, we created a niche for ourselves,” he says.

The pharmacy also offers pediatric vaccinations to distinguish itself from its competitors.

From the start, Song says his pharmacy also worked to establish relationships with area physicians, many of whom still refer business to the pharmacy today.

“There’s a lot of competition at least in the Dallas area, and some of the physicians are getting out of these services. So because we have such a good relationship with them, they call us and say, ‘Hey, do you want this clinic?’ ” Song says.

Bruce Kneeland, a consultant to independent community pharmacies, says one of the biggest hurdles for many
pharmacies is still the fear that they will upset physicians by offering vaccinations. However, pharmacies need to be proactive about meeting with physicians and communicating their desire to be partners in healthcare rather than competitors, he says.

Maximizing Your Patient-Base

In addition to targeting new niches, pharmacies can also increase the number of immunizations they do by focusing on their existing patients.

Laura Patterson, PharmD, owner of Hale Center Clinical Pharmacy in Hale Center, TX, says they use several strategies to look for vaccination opportunities among patients already enrolled in other pharmacy programs.

For instance, every month before her technicians call patients in the pharmacy’s medication synchronization program to review their current medication list, they also evaluate whether they have outstanding vaccinations that could be completed.

The same strategy is used to remind customers about the pharmacy’s diabetes education program and medication therapy management patients.

If a patient is identified who may need a vaccine, the pharmacy then is able to deliver the vaccine when the customer is already planning to come into the store to pick up their medications.

“The techs get the consent and disseminate the vaccine information sheet and get the vaccine run through on their insurance to be sure it’s covered,” she says. “They cover all that and then it comes through to the pharmacist.”

Once the pharmacist is involved, they review the vaccine, make sure the customer has the education they need, and administer the vaccine.

There are other staff considerations as well. Meyer says his pharmacy frequently provides off-site immunization services for businesses or other community groups. To accommodate this, on Monday, Wednesday and Friday the store has three pharmacists on duty, giving him an opportunity to leave the store if necessary.

Administration of Vaccines

Now that customers have more choices when deciding where to get their vaccines, pharmacies also need to put effort and energy into ensuring their environment and process is customer-friendly and appealing. In addition to having a private area to administer vaccines, experts say pharmacists need to have a good bedside manner to make the experience as pleasant as possible for an array of customers who have different comfort levels with shots.

Meyer says pharmacists should develop a really good technique for giving a shot, and be empathetic and sympathetic when patients voice concerns, such as if they are having a negative reaction after the shot is given.

“Sound like you care—and you really do care—and maybe you’re going to go that extra mile to help them out to try to get this reaction or whatever they are having resolved,” he says.

As more pharmacies and retail stores begin offering vaccination services, pharmacies can stay competitive by finding ways to distinguish themselves from the pack to keep old customers coming back and new ones entering the door.
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How to Achieve Balance in Work and in Life

Stress is unavoidable, but you can identify and overcome burnout before it impacts you

By Karen Berger, PharmD, contributing writer

Stock Photo: Leigh Prather

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“Mine!”
“No, it’s mine!”

After listening to my children argue regularly for hours, my nerves were frayed and I was frustrated. I looked around the messy house: toys scattered everywhere, piles of clean laundry to be folded, and a sink piled high with dishes. I was looking forward to going to work that evening because I knew that I would feel more in control of things at work than at home. As a floater at a chain store at the time, I sprinted out of the house when my husband got home and happily drove to work.

But that evening, I wasn’t particularly in control at work, either: A seasoned tech was out sick, and the pharmacy was staffed with new hires who were limited in capability. The staff was 100 prescriptions behind when I walked in the door, and I knew immediately that there was no hope of having a good night. Every prescription was rejected or had some kind of problem, and every patient needed a flu shot. Although I knew how to resolve every issue, there was no way of catching up and keeping up.

I felt overwhelmed—my home life felt out of control, and I was feeling the same way at work. I wanted to be a Pinterest mom, one of those women who seem to juggle work and family life effortlessly, who send their kids to school with perfect bento boxes and craft Instagram-worthy art together.

Pharmacy is an incredibly stressful job, where any mistake can be fatal. On social media, you can see the reality firsthand. As a group, pharmacists are more stressed out, burned out, and overworked than ever. The 2018 Drug Topics Salary and Job Satisfaction Survey reveals that 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 most entire households. Two-thirds of pharmacists say they have more stress compared to last year, and 72% said workloads are higher, too. (Search “survey” on our website for the full survey results on compensation and professional satisfaction.)
Searching for Balance
What is work-life balance, and why is this elusive paradigm so important to our mental health and physical well-being?

Stress levels soar when work life and personal life are unbalanced. According to researchers at the Mayo Clinic, the consequences of poor work-life balance include:
- Fatigue, which can lead to reduced productivity as well as inability to think clearly, which can in turn lead to dangerous mistakes.
- Poor health, since stress can compromise the immune system and worsen ongoing medical conditions. It also increases the risk of substance abuse.
- Lost time: Working excessively and missing family events can leave one feeling left out and may harm relationships with loved ones.
- Increased expectations: Those who work extra are often given more work and responsibility, creating a never-ending cycle.

According to a 2017 article in *Harvard Business Review*, the psychological and physical problems of burned-out employees cost the healthcare system between $125 billion and $190 billion per year.

Jennifer Surak-Zammitti, LCSW, a psychotherapist and a certified school social worker at Baker Street Behavioral Health, says stress tends to be difficult to avoid at work. “This stress can trickle down into our personal lives, causing havoc among our relationships with others and ourselves,” she says.

She says preparing for the day is important. Taking time before work to relax by having a cup of coffee and breakfast while watching TV, listening to music, or reading, is a great way to start the day.

Even the choice of clothing can help. “Dressing for success is about dressing for the success of feeling good—pick out some nice clothing that makes you feel good,” Surak-Zammitti suggests. For example, even if you wear a uniform, consider small things such as fun socks, unique jewelry, or

Clarissa Hall, PharmD, is pharmacist-in-charge at Sinks Pharmacy in St. Clair, MO, one of 13 pharmacies. Hall is also a wife, mother of two boys, and owns a virtual franchise. In addition to serving as a regular community pharmacy, her pharmacy compounds for all 13 locations. Hall oversees all activities of the day-to-day function of the store, manages staff, supervises compounding, and fields compounding questions from all 13 locations. She is also involved with hormone consulting, making recommendations to physicians for their mutual patients.

To keep things under control at work, Hall blocks time slots to accomplish certain tasks, completing tasks as soon as assigned rather than procrastinating. Delegating tasks is essential. “There are no bad days, just bad moments,” she says. She praises her coworkers frequently when they have done well, and they are proud to hear they have done a great job.

“Create a culture that radiates to your patients,” she says.

Up until a few years ago, Hall would run around like a “crazy woman” trying to get everything done. “Although I was functioning, I was exhausted beyond measure and looking for an alternative to the chaos,” she says. She decided to take control of her life after reading a book called “The Big Leap” by Gay Hendricks. She also learned about blocked time, where every important thing in her life gets scheduled. Hall has time blocked for work, family, and her side job with the franchise. She makes it a priority to schedule date nights with her husband. Within the blocked time slots, Hall does a modified form of bullet journaling.

“It is extremely important for me to start every day with quiet reflection, gratitude, and to read something inspirational,” she says. Box breathing—taking slow deep breaths—is also a tactic she employs when things seem overwhelming. “I have learned if I stay calm, it will reflect on those around me.” Spending time on Sunday evenings planning her week and meal prepping has helped manage the hectic weekday schedule.

“Since I am now in control of my time and it doesn’t control me, I don’t feel exhausted and overwhelmed. It is all a mindset and when you are able to set your mind to positive thinking, everything falls into place. I chose to make a change by investing in me and I am forever grateful I did.”

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Surak-Zammitti also recommends making your bed before you leave, as this is the first step to completing a task for the day. While commuting to work, listen to music, blast it if you want. Whatever music makes you feel upbeat and motivated is the perfect music for your drive.

Once at work, be sure to greet your coworkers, and ask about their evening or weekend. Small talk helps set the mood for the environment, making it relaxed and less stressed.

Now that you have set the stage for a less stressful day, be ready to focus on your work. Although there is no way to avoid the work ahead, having tools that help you cope on hand can be helpful. Having a piece of candy or gum, or a favorite drink on hand can make a bad moment better, even if briefly. Imagine having a stressful day and then you remember that your favorite drink is in the refrigerator, so you grab it, and for a few moments you feel a bit of joy and relaxed.

Knowing that finding time to eat a meal or even use the bathroom can be difficult in many pharmacy settings, Surak-Zammitti offers pharmacists some small tips. Whenever possible, taking small breaks throughout the day, such as bathroom breaks and fresh air breaks, if your workplace allows you to step outside, will help you recharge. Although on many days you may not be able to take a 30-minute lunch, take a few minutes to sit down and eat a sandwich.

Making jokes and laughing with coworkers throughout the day is another huge key to making the workplace happier. “Laughter is proven to boost our moods, which will then improve our productivity,” she says.

When the day is over, take time to decompress. “The drive home is our tool to transition,” Surak-Zammitti explains. Again, blast your favorite music on the way home and sing along. Surak-Zammitti suggests taking a longer route or driving around the block a few times if you have a short commute to reduce stress before walking into your home.

Patty Taddei-Allen, PharmD, MBA, BCACP, BCGP, is the director of outcomes research at WellDyneRx. In the managed care environment, Taddei-Allen analyzes, interprets, and organizes clinical and financial information. She crafts and delivers WellDyneRx’s clinical value proposition and develops and implements clinical programs for both the PBM and its specialty pharmacy.

“The most stressful aspect of my job is the amount of updated clinical information to stay abreast of, in addition to the ever-changing marketplace, to ensure that we are delivering the lowest costs and improved clinical outcomes for our members and our clients.”

Taddei-Allen stays motivated at work because she feels it is an exciting time for pharmacy, with many changes expected in the next 5 to 10 years. Taddei-Allen also credits her work-life balance in helping her manage stress at work. Her supportive spouse is critical to this balance. “We truly work as a team, with both of us taking on household chores or tasks such as taking a child to the doctor.” Because her spouse is a pro at handling bedtime, Taddei-Allen has been able to take adult ballet and jazz dance classes several nights a week. “I’ve been dancing now for 4 years, and it’s been a great way for me to destress from everything,” she says. She is also very involved with her kids’ school, serving on the PTA board and organizing activities for the students.
Since work is filled with stress, it is important to have a home filled with as little stress as possible. Having a clean and organized home is essential. Hire a cleaning service and/or even a laundry service to help you free up some time at home. Planning meals ahead of time is also helpful, Advance meal prep, slow-cooker meals, or quick and easy recipes can help with those mealtimes that you are too exhausted to cook.

Surak-Zammitti advises: "Being honest with your family is also key. Let your significant other know about your stress and what will help you when you come home. Same goes for the kids, letting them know about your day and how you may need some time when you get home helps build empathy in them while helping reduce stress for you."

Once the night comes to an end, crawling into the bed that you neatly made that morning will feel extra relaxing, as sleeping in a bed that was made has been shown to improve sleep. Sleep quality can also be improved by changing your sheets weekly, keeping your bedroom dark and cool while sleeping, and investing in a comfortable mattress, sheets, and pillows.

Surak-Zammitti recommends that on your days off, do whatever makes you happy and feel at peace. "Do your best not to discuss work and if you bring work home, hide it out of sight," she says. Plan fun outings with spouses, family, and friends because looking forward to such events during the week can help reduce work stress. Surak-Zammitti knows that it may not be possible to make all of these changes at once. It also may take a while to implement enough changes to feel a difference in your stress level to the point where you are enjoying a healthy work-life balance. Making even a few of these changes can help reduce stress.

If your stress levels are serious, try talking to a social worker or psychologist, who might be helpful for offering personalized advice and coping skills as you navigate toward a healthy balance.

Karen Berger, PharmD, balances her work at an independent pharmacy with her life with her husband and three children in northern New Jersey.

Larry Riggi, PharmD, is a pharmacy manager at a Walgreens. Riggi finds it challenging to find a balance between filling prescriptions and performing managerial duties to ensure the team hits all their numbers. To stay motivated at work, Riggi compares his store to other similar-volume stores, trying to be the best. He enjoys passing along praise from management to his team. Riggi has a strong support system of his wife, Megan, and three friends who are all pharmacy managers who bounce stories and ideas off of each other.

Riggi finds time management and a great work-life balance to be critical to keeping stress at bay. Larry and Megan coordinate schedules to have most of their days off together. On those days off, they try to pack a lot of activities in for the kids. "It’s not fair to the kids that we have these odd schedules, so we try to do as much as possible with them," he says. Knowing that he has days off with family to look forward to helps him get through stretches of longer shifts.

The Riggi family has season tickets to the Buffalo Sabres, and they go to 10 games a year. They also enjoy spending time together at the zoo and museum. Riggi and his wife schedule date nights when they can, and Riggi also spends time with friends playing XBox. In the summer, Riggi enjoys fresh...
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air and time out on the golf course. “For me, spending time with my kids, my wife, and my family is the best way for me to deal with the stress.”

Riggi thrives on keeping busy and enjoying activities with his family. “I don’t think I’ve had a weekend off to do yard work or watch a football game in at least a few months, and I wouldn’t trade that for anything after seeing the joy on my son’s face when we take him to the zoo or on a train ride. It’s all worth it in the end, working this crazy schedule, to be able to provide and give my children a wonderful life.”

Laura Dee, PharmD, is a clinical pharmacist at a federally qualified health center in Illinois. Dee finds it very stressful to be “a department of one,” as the only full-time pharmacist across eight clinics. Also, it can be challenging at times to change people’s perceptions of a clinical pharmacist’s scope of practice.

For Dee, it is the patients that keep her motivated and going strong. “No matter how much stress I have at work, my patients are thankful for me and I am thankful for them. No matter what kind of day I am having, these grateful patients help me stay centered, and remind me why I’m a pharmacist.”

Dee credits her Monday-Friday, 8 a.m.-5 p.m. schedule with allowing her to have “a life outside of work.” Although she sometimes spends extra time at work with direct patient care, she tries not to take her work home.

“At the end of a work day, I like to come home and recharge,” Dee explains. A self-described introvert, she enjoys reading and volunteering with animal rescue organizations. Fostering for animal rescues—cats in particular—is a great stress reliever for Dee. “It’s a wonderful feeling to gain an animal’s trust and become so important to them,” she says.

Dee also participates in a bowling league with coworkers and friends. “I’m absolutely terrible at the bowling, but it’s a fun and humbling experience,” she says. “I mean, where’s the fun in being good at everything?”

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By Keith Loria, contributing writer

Pharmacists and others who work in the pharmacy industry are a unique hybrid of caregiver and scientist. In their daily work, the science aspect is often emphasized, but the client or patient is the one that benefits from the caregiving role.

Jan L. Bowen, a life coach and founder of Strategic Solutions Services, says the difficulty with that hybridization is that as a caregiver, the “well” from which one gives can often run dry.

“It’s crucial to replenish yourself—to fill the well, so to speak—in order to continue successfully doing your job and keep giving,” she says. “Work is only one aspect of life. We need various aspects of life to stay mentally, physically, emotionally, and spiritually—however you define that—healthy.”

Mary Loverde, a work-life balance expert and author of I Used to Have a Handle on Life, But It Broke, says if you think you have too much to do and not enough time to do it, this is not your imagination, and it doesn’t mean you have failed in some way.

“It’s important to create a new definition of life balance, she says. “Instead of trying to get it all done, adopt a new life balance motto: ‘When you can’t keep up, connect.’ Connection is what creates a balanced life: Connecting with yourself, your family, friends, community and your God.”

A great way to do this, she says, is to establish some rituals that connect you with what is most important to you.

“For example, make the first Saturday of each month movie date night and be sure it put on the calendar,” Loverde says.
“Tell your kids that Wednesday nights are go-for-a-hike night. Figure out what feels good. Meaningful rituals give us the predictability and stability that make us feel safer and more connected in what feels like a very unpredictable and unstable world.”

Joe Robinson, a noted work-life balance speaker with Optimal Performance Strategies, says the life side of the work-life balance equation won’t happen by itself. People need to commit to making changes in their lives, including dipping their foot in the “life water,” and trying some new activities like dance or tai chi, he says.

“You have to look at the areas at work that are draining you in terms of demand, stress, and productivity that you can’t keep up with, and make adjustments in your work style,” he says. “You also need to carve out time for work recovery, so when you go home at night, you have strategies to relieve the stress and recharge the brain.”

Robinson says some great ways to remove stress from the day are unplugging from email once you go home, dedicating time to a hobby or exercise, and spending time with loved ones doing things you enjoy.

“If there’s a passion that you take part in regularly, you can add eight hours of joy in your week, and that goes a long way to relieving stress,” he says.

Jeff Davidson, who trademarked himself as the “Work-Life Balance Expert,” says it’s vital to periodically abandon the rat race and make time for yourself. He is author of Dial it Down, Live it Up.

“The typical professional sacrifices rest and reflection in the hope of getting more done. Those with work-life balance take time for rest and reflection throughout the day, and accomplish more as a result,” he says. “Ways to accomplish that include drawing upon self-calming rituals all day long, lingering a moment after lunch, centering yourself on the way to breaks, and even between tasks and sleeping eight hours a night.”

Tips for Change

Change, especially for workaholics, isn’t easy, so taking small steps toward establishing clear priorities, supporting them, and assembling resources to accomplish objectives is the best way to go. Loverde suggests looking at your existing routine and modifying one element that would have the greatest impact for you.

Bowen recommends reflecting on all areas of life: fun/leisure, relationships (family/friends), home/physical environment, personal/spiritual development, finance/wealth, and career/work, and figuring out what feels complete and what areas are lacking.

“If you consider each of these areas a spoke in a circle, this can be a representation for a wheel of life. The wheel needs to be in balance in order to run smoothly,” she says. “Then focus on one area that will be the most impactful to change. And start by committing to a morning and evening routine for yourself. That routine will be designed according to your needs, so only you know the perfect routine that will suit.”

Some of Davidson’s tips for removing stress from one’s life include going a whole weekend without reading anything, scheduling a spa treatment, writing and calling friends you haven’t seen in a while, or visiting a botanical garden to enjoy the flowers, and letting your sense of smell, rather than your eyes and ears, dominate for a change.

“Another idea is to walk around your yard barefoot like you did when you were a kid. Feel the grass between your toes. Stick your feet in dirt or in a puddle,” he says. “Establish life priorities and pursue them daily. It will make a big difference.”

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Dietary supplement use continues to grow in popularity. In 2017, 76% of U.S. adults reportedly used dietary supplements—a 5% increase from the previous year and an all-time high, according to a survey conducted by the Council for Responsible Nutrition. WHO estimates that 80% of the global population uses some form of herbal medicine. Domestically, the nutraceutical industry has also enjoyed a surge in popularity, partly spawned by growing public discontent with traditional Western medicine. In addition, some patients view OTC products and dietary supplements as a more convenient and/or affordable alternative to seeking medical treatment or as a suitable treatment for minor conditions.

The uptrend in dietary supplement use creates unprecedented opportunities for pharmacists working in many practice settings where they can alter the patient experience by ensuring appropriate use of these products. While pharmacy students receive education on OTC products, training varies greatly among schools of pharmacy, and pharmacists might lack sufficient knowledge about OTCs.

OTC Education Is Complicated
The Accreditation Council for Pharmacy Education (ACPE) requires that pharmacy students receive training in what it refers to as “natural products and alternative and complementary therapies.” ACPE defines this training as the “evidence-based evaluation of the therapeutic value, safety, and regulation of pharmacologically active natural products and dietary supplements,” while also acknowledging cultural practices of providers and their patients to encourage healthy habits and practice.

While the ACPE mandates that pharmacy schools provide education on OTC products, it does not require a certain number of hours for OTC education. The amount of nonprescription dietary supplement education varies tremendously between schools and remains a difficult undertaking given the myriad of dietary supplements on the market. “There are an estimated 70,000 supplements worldwide from which consumers may choose, so it’s hard for healthcare professionals to figure out which group of supplements to focus on for clinical indication, side effects, and place in therapy,” says Cathy Rosenbaum, PharmD, MBA, CHC, a holistic clinical pharmacist and founder/CEO of Rx Integrative Solutions in Blue Ash, OH. “There’s a vast difference among clinical research related to American, Chinese, and Ayurvedic herbs, in addition to homeopathy and other nonvitamin supplements that are used for condition management or wellness/prevention.”

Challenges with Evaluating Quality
Traditional Indian medicine, or Ayurveda, and traditional Chinese medicine are among the oldest forms of medicine, and their popularity has transcended their Asian origins, with global market growth predicted at a rate of 5% to 10% annually, according to the peer-review journal “Evidence-Based Complementary and Alternative Medicine.”

Recognizing the market potential, the FDA passed the Dietary Supplement Health and Education Act of 1994 (DSHEA), designed to prevent mislabeling and misbranding, and published regulatory documentation guidance in efforts to address quality challenges stemming from the use of herbal medicine. While DSHEA expanded the market of dietary supplements by including vitamins in its classification, the FDA does not evaluate these nonprescription products for safety, but charges the manufacturers with ensuring the products are safe.

“From a practical perspective, dietary supplements are considered safe until they’re proven unsafe under DSHEA, which is just the reverse with prescription medications,” Rosenbaum cautions. Due to potential quality/safety risks with supplements, “buyer, pharmacist, physician, and healthcare provider beware before purchasing or recommending supplements for yourself or your patients,” she says.

John Ayo, a naturopath and CEO of Travel Balance, emphasizes the
importance of healthcare professionals exercising their due diligence when reviewing product quality—especially when evaluating the potency and purity of herbal products. “Selecting quality herbal products can be tricky because you have to consider many factors, including whether the product has been standardized, how it was processed, the growing conditions, and when the plant was harvested,” Ayo says.

To help overcome these hurdles, Rosenbaum recommends pharmacists use three steps to ensure the potency and purity of a product:

1. **Determine if the product has undergone quality or potency and purity testing by an independent third party.** Rosenbaum says the product labels should bear seals from either the United States Pharmacopeia (USP), the National Science Foundation (NSF), or ConsumerLab.com.

2. **Request a quality specification sheet for potency and purity from the manufacturer, called a Certificate of Analysis (CoA).** “Most people don’t realize that we as pharmacists have the ability to get a CoA,” says Rosenbaum. To answer any questions not provided in the CoA, Rosenbaum recommends calling the manufacturer to gather information about its product testing. Ask what testing methods are used, such as chromatography, mass spectrometry, gas chromatography, or titrimetry? What additional levels of testing are done? In early 2018, the NSF International began offering DNA verification of raw ingredients, known as a DNA-authenticated mark, to help reduce concerns regarding fraudulent products infiltrating the market.

3. **Review published human clinical studies.** For supplement indication, side effects, and drug/supplement interactions for the supplement formulations that have been standardized in the industry.

### Check Interactions

“Pharmacists play a tremendous role in helping to communicate when patients are on something that doctors don’t know about,” Andrew Freeman, MD, FACC, FACP, a cardiologist, co-chair of the Nutrition and Lifestyle Workgroup of the American College of Cardiology (ACC) and director of cardiovascular prevention and wellness at National Jewish Health in Denver.

The intimate patient-pharmacist relationship coupled with pharmacists’ educational training empower them to evaluate the potential for herbal-drug and nutrient-drug interactions, but determining interactions is only one part of the puzzle, says Rosenbaum. According to ACPE standards, pharmacists must make prudent recommendations for supplement use based on evidence, which often is not as easy to find or as thorough as that for prescription pharmaceuticals. Because herbal-drug interactions have not been studied as widely as drug-drug interactions, the best available evidence might be a case report.

Rosenbaum points out that pharmacists’ training in evaluating clinical research studies for supplements, the patient’s laboratory results, and recommending dosing adjustments and/or cost-effective alternatives are a value-added professional service. Advice from pharmacists can fill the gap among health food store clerks, nurses, dietitians, chiropractors, and physicians. Pharmacists have another layer of professional responsibility when determining whether supplementation is necessary. For example, patients who take metformin should not take vitamin B12 without having levels of this vitamin tested first. Similarly, CoQ10 supplementation may not be appropriate for every patient taking statins. If a patient has muscle pain while on statin therapy, Rosenbaum recommends evaluating other potential sources of the patient’s pain and/or requesting the primary care physician write an order for a CoQ10 blood level before automatically recommending the supplement.

Another complication in managing medication-related nutrient deficiencies is the need to evaluate the patient’s diet. “How does the pharmacist know if the patient truly needs CoQ10 supplementation?” Many foods such as broccoli, cauliflower, pork, beef, chicken, strawberries, and peanuts contain CoQ10, he notes.

Rosenbaum offers readers some final advice: “Your recommendations should be understandable, evidence-based, practical, and readily actionable for your patients.”
The Pros and Cons of Switching to a Health System

By Karen Appold, contributing writer

Working at a health system pharmacy has its perks when compared to working in a community setting. For one, health systems are where pharmacists tend to make the most money, according to the Drug Topics 2018 Salary and Job Satisfaction Study. The survey found that 82% of hospital pharmacists make more than $120,000 annually compared to 71% of all pharmacists, and 25% make at least $150,000. This means health system pharmacists are almost twice as likely to earn salaries in the top range for the profession than pharmacists as a whole.

But it is health system pharmacists’ responsibilities and opportunities that make their jobs most rewarding. In fact, the annual salary survey reported that only 15% of health system pharmacists were dissatisfied in their work compared to 27% of all pharmacists.

Health system pharmacists cite a variety of reasons for making the switch from community pharmacy. Emily Griesbach, PharmD, BCPS, at University of Wisconsin Health, Madison, Wisconsin, decided to pursue being a health systems pharmacist to grow her clinical knowledge and become involved with managing more acute disease states. “I can use what I learned in pharmacy school more fully,” she says.

“A huge benefit of working as a health systems pharmacist is being directly involved in the patient’s healthcare team,” Griesbach says. “I work alongside physicians and advanced practice providers to develop care plans and make medication recommendations during daily rounds. Being visible to these providers helps foster relationships, which in turn leads to clinicians asking pharmacists for their opinions and recommendations.”

Besides having more time to spend with patients, Panteha Kelly, RPh, BCACP, CDE, clinical pharmacist specialist and assistant clinical professor of pharmacy, University of California San Diego Health, La Jolla, says her work hours are also better. “At the community pharmacy, I worked until 9 or 10 p.m. some nights and every other weekend. Now, as I gain seniority, I can choose from variable shifts and transition to shifts that are more desirable.”

And with more technicians and clerks assisting with prescription processing, Kelly has more time to focus on patient care rather than being more involved in the business side of the practice and completing tasks such as prior authorization approvals from insurance companies or prescription order entry.

When she worked as a community pharmacist, Susan Alsaras, PharmD, pharmacist at the Hospital for Special Surgery in Manhattan, says the focus was entirely on selling prescriptions, refills, offering 90-day prescriptions,
and verifying orders fast enough to keep up with demands of statistical requirements.

Working as a health system pharmacist differs from community pharmacy in other ways, according to pharmacists who made the change.

**Patient interaction and counseling:**
In a community pharmacy, patient interaction was abundant, but rushed, Alsaras says. "Patients didn’t want to be bothered with discussing their new medications," she says. "And they often targeted me for insurance mishaps. Patients at HSS usually listen, ask questions, and seem satisfied with pharmacist responses when counseled."

**Developing care plans:**
With access to each patient’s electronic medical record at a health system, it is much easier to determine if the selected therapy is appropriate for the patient, Kelly says. At a community pharmacy, this access is not always readily available.

**Consulting with physicians, nurses, and other professionals:**
Health system pharmacists work more frequently with other care team members, says Ryan Foster, PharmD, MBA, senior director of pharmacy at Spectrum Health, Grand Rapids, MI. They bring a specialized set of skills and knowledge to the team and can integrate it into decision making much earlier in the process.

Griesbach says it’s easier to consult and work with other healthcare providers, especially physicians, when working as a health systems pharmacist because they often work with the same people each day and can build rapport.

**Providing specialized services:**
In community pharmacy, you are a "jack of all trades," you know a little bit about a lot of medications, Griesbach says. As a health systems pharmacist, you can carve out a niche in an area of great interest. However, additional training may be required such as a second or third year of residency.

Kelly says a health system offers the opportunity to work in a variety of specialties such as geriatrics, internal medicine, oncology, diabetes, and administration, and provides many career opportunities. "At UC San Diego Health, my interest in diabetes led me to start a diabetes self-management program, which the pharmacy department supported," Kelly says. "Our accredited program allows us to bill for services and not only garner additional revenue but also practice at the top of my pharmacy license. Our organization has employed numerous clinical pharmacists who are involved in different specialties and work side by side with other healthcare providers."

By working at a hospital that deals solely with surgery and orthopedics, anti-coagulation and infectious disease are topics that Alsaras largely provides information on to physicians, prescribers, and nurses. In addition, she compounds medications, often for intravenous use, which she rarely did as a community pharmacist.

**Involvement in research:**
Health system pharmacists have many opportunities to participate in research as well as quality improvement, especially at larger academic institutions, says Griesbach, who championed a bariatric quality improvement project.

**Tips for Success**
For pharmacists considering which path to take, Foster recommends they reflect on whether they prefer to work with patients more longitudinally, which community pharmacists do, or if they would rather be more involved with acute episodic care, which health system pharmacists do.

In order to build a successful career in health system pharmacy, pharmacists need to first establish a high degree of trust with their pharmacy peers and other members of the healthcare team, Foster says.

Along these lines Alsaras adds, "Work together with your colleagues, ask each other for advice and maintain a cordial, professional relationship."

Pharmacists who are interested in a career change should research their path of interest, learn what it takes to get there, and not be afraid to take risks to make a change, Kelly says.

Griesbach says it’s critical to know your resources. "Not a day goes by without being asked a question for which I don’t have the answer," she says. "It’s fine to say, ‘I don’t know the answer,’ but then I go and find it in a timely manner."

When offering a recommendation to a physician, word it thoughtfully and concisely. "Physicians are constantly busy and are appreciative (and will more likely listen) if you’re short and to the point," Griesbach says. "Also, don’t be discouraged or take it personally if your recommendation isn’t accepted."

Flexibility is another key. "Drug shortages, clinical guideline changes, and formulary changes are just a few challenges that you encounter every day as a health system pharmacist," Griesbach says.

When reflecting on making the change, Alsaras says, "Learning something new each day, working together with a team to provide the best possible care for patients, and being someone who everyone relies on for drug information gives me a sense of pride and success that I never felt when working in community pharmacy. Although I enjoyed the frequent interaction with patients that was prevalent in community pharmacy, I had much more to offer patients and physicians. Switching to a health system pharmacy was one of the best decisions I have made."
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Retirement is the welcome and well deserved finish line for many pharmacists after a successful career. But the milestone requires careful consideration—and years of planning—to fully realize the best financial and mental benefits retirement can bring.

Before a pharmacy owner can walk out the door for the last time, there are legal, financial, emotional, and pharmacy management considerations that should be addressed and specific steps that should be taken to promote a smooth transition from one owner to another.

“There’s a lot of pharmacists near retirement age who don’t necessarily have a retirement plan or succession strategy,” says Charlie Le Bon, Director of Pharmacy Ownership Services for AmerisourceBergen.

The biggest mistake most pharmacists make is underestimating the amount of time it will take to prepare their pharmacy for succession or a sale. Experts recommend that pharmacists begin preparing for retirement three to five years before they plan to leave. By preparing in advance, pharmacists are able to find a suitable successor if they desire, identify areas of weakness within the business and optimize operations to improve their profits during a sale.

Succession Planning Versus Replacement Planning
One of the first steps out-going pharmacists need to consider is how they want to exit the industry. According to Ben Coakley, director of business development for Waypoint Rx, there is a significant difference between succession planning and replacement planning.

“It’s like dating. You have to go through the dating process to learn the new successor and whether he or she has the values that you share. That’s the most important part when it comes to succession planning.”

Succession planning is a comprehensive exit strategy that allows a pharmacist to make sure his or her values are still incorporated into the pharmacy after departure. “Succession planning is when you are preparing your successor, preparing the pharmacy,” Coakley says. “You are doing employee retention and you are doing a lot of these things because the owner says ‘I want a little bit of say in how this goes.’”

Replacement planning, on the other hand, is simply selling a pharmacy, which focuses more on preparing for the actual transaction rather than working in collaboration with the new owner to smooth the transition before the sale.

True succession planning, Coakley says, is a way for the selling pharmacist to ensure his or her values are maintained in the new ownership.

“It’s like dating,” he says. “You have to go through the dating process to learn the new successor and whether he or she has the values that you share. That’s the most important part when it comes to succession planning.”

According to Coakley, most pharmacists typically want succession planning, but it can be a difficult and timely process, leading many to end up with replacement planning instead.

Waypoint Rx has developed a tailored program known as Transitions Rx to guide owners and new buyers through the succession process, including the pharmacy, legal, financial, and emotional aspects of the transition.

Le Bon says the overall selling process for pharmacies can take anywhere from six months to five years and can be
hindered by any number of challenges, including geographic, financial, or business operation issues.

“It varies substantially. Part of it is you have to find a buyer that’s a right fit,” he says.

Optimizing the Financial Picture

Many retiring pharmacists may have a certain dollar figure in mind that they hope to sell their business for, but just like in a home sale, a business is only worth what a buyer will pay.

To optimize the profits from a sale, pharmacists need to spend time and resources before selling a pharmacy to streamline operations, maximize profits, and make cosmetic improvements to the store.

“It’s kind of like curb appeal with your house. It’s curb appeal as it relates to your pharmacy and you want to pretty it up if you can,” says Bill Popomaronis, BSPharm, vice president of professional affairs for NCPA.

Arriving at a Fair Price

As part his responsibilities, Popomaronis helps buyers and sellers arrive at a fair and responsible price for a business. He recommends sellers make themselves more valuable to the bank handling the sale by creating a lean inventory, making sure the pharmacy is buying at the best price by partnering with an aggressive wholesaler, and making the payroll as efficient as possible.

Le Bon says the best way for pharmacists to gain a better understanding of their current operations is to undergo an outside business evaluation that can help the pharmacy create an individualized set of recommendations to maximize both efficiency and profitability.

“If they are able to plan ahead accordingly, and work to increase the efficiency of a business, ultimately, we help increase the sales price when it is time to retire,” he says.

Popomaronis also recommends pharmacies “normalize the books” by looking at NCPA benchmarks, assessing what is a fair and reasonable price, and assessing the one-time nonrecurring extraordinary expenses that a seller may have put in, but that won’t be expected by the new owner. These expenses are typically found on the expense side of the ledger and are added back into the profit, he says.

“The greater the profit, the greater the price for the business,” Popomaronis says. “A $3-million store that has a 5% normalized net profit will not be as expensive as one that is at 8%.”

One factor working in favor of sellers is that community independent pharmacies continue to be a sought-after commodity.

“I would say, in terms of a ratio, it’s probably two to one buyers to sellers,” Le Bon says. “There’s definitely an appetite and a hunger for pharmacists to own their own business and to play that role as a critical part of a patient’s journey.”

Easing the Transition

Experts say pharmacists can also employ strategies to help ease the transition from one owner to another to help increase the probability that the pharmacy will continue to succeed under new ownership.

Some pharmacy owners choose to continue to work at the store in a part-time capacity to not only help answer any lingering questions but also to assist with customer retention.

Coakley says there are typically two types of responsibilities in any business: ownership responsibility and management responsibility. Most owners looking to sell a business are tired of the management responsibility, including payroll, billing, and scheduling.

“A lot of times in succession plans, we transfer [management responsibilities] first,” he says. “We need to make sure the new owner can run the business and that mentally they are capable of handling this before we give them the ownership control.”

Other owners prefer to exit on a set date.

1,569

Number of independent pharmacies that opened in 2018, including those that changed hands.

Source: NCPDP and NCPA

One of the biggest obstacles facing pharmacists reaching the end of their career is reaching burnout before they are able to put the steps or pieces in place to hand off the pharmacy in the way they had hoped.

Experts say by planning early and relying on experts to help, pharmacy owners can ensure their life’s work is able to continue under new ownership and leave a lasting legacy.
The first time I met Ida, an outgoing, warm-hearted woman in her mid-80s, she shuffled into my office for a comprehensive medication review (CMR). She ambulated stooped over on a rolling walker, her husband dutifully tagging behind her with her purse and paperwork.

Ida, a pseudonym, was the kind of person who smiled as much with her eyes she did with her mouth. As soon as we locked eyes, the walker and her stoop—and Ida’s agony—melted away. We had an instant patient-provider connection.

During the CMR, Ida told me that her ambulatory challenges resulted from an adverse drug reaction that had left her bedridden and in the hospital for months. Her long road to recovery included arduous physical therapy. Although she eventually regained the ability to walk, she required assistance.

Over the next few months, I became Ida’s personal pharmacist. She called me for drug information and even requested that I serve as her advocate when her insurance company asked her to change to cheaper medications.

I was a recent graduate at the time, and earning Ida’s trust boosted my confidence as a new pharmacist.

A few months after Ida’s CMR, I saw her husband standing in line at the pharmacy.

“I wonder how Ms. Ida is doing,” I said to Dan, also a pseudonym, the other pharmacist on duty.

After a brief pause, Dan said: “She died.”

I froze. Overcome with a sudden wave of grief and shame, I left the counter and hid between the pharmacy shelves like a scolded puppy licking its wounds.

“Frieda, it wasn’t your fault,” Dan tried to console me. “Her husband thinks the world of you.”

Ida wasn’t a relative or a close friend, but neither of these factors softened the sudden blow of her passing. Toxic thoughts began to flood my brain: What could I have done differently? Was it even appropriate for me to feel sad? Is it acceptable to ask my colleagues about how they cope when they lose a patient? I felt too ashamed—and stupid—to ask.

It was truly an awkward moment in my career: questioning whether my feelings were appropriate and not knowing how to process them. I would eventually learn that the emotions I experienced that day were OK, and that they are normal.

Grief and Self-Blame

When a patient dies under the normal provision of care, healthcare workers may struggle with strong emotions including grief and self-blame, according to Brady Shuert, project manager with Christiana Care Health System’s Center for Provider Wellbeing, where he directs their peer support program, Care for the Caregiver.

For Andrea Seitzman-Siegel, PharmD, a clinician whose experience includes various hospital settings as well as telemedicine, circumstances and the type of practice setting sometimes amplifies the emotional toll on the pharmacist.

“I have attended codes with family present when the patient dies. I have a much harder time dealing with that than if the family was not present,” says Seitzman-Siegel, a clinical advisor at Optum. “There is something about having the family there in the room that reminds me that this is not just a patient, but someone’s loved one.”

Seitzman-Siegel also says the impact of patient death intensifies when a child dies. She recounted an incident that involved a child who drowned and who was about the same age as her own son. Witnessing the medical team exhaust all options to save the child’s life, coupled with the parents’ reactions, devastated her.
“It’s hard to completely detach yourself from a patient emotionally because you develop relationships.

Acknowledging sad feelings is both normal and human.”

JUDITH A. SMITH, PHARMD

“IT changed the way I viewed my own child,” says Seitzman-Siegel. She signed her son up for swim lessons that week. While she took measures to help ensure the future safety of her own child, she didn’t take action to address her emotions.

“The people at the code were given the option of counseling. While I didn’t attend due to scheduling, I think it would have been helpful,” she says in retrospect.

“Pharmacists risk burnout if they bury their feelings and don’t acknowledge them,” warns Judith A. Smith, PharmD, BCOP, FCCP, an associate professor at the University of Texas Science Center at Houston Medical School.

As an oncology pharmacist who frequently works with dying patients, Smith says expecting practitioners to become desensitized is unrealistic. “It’s hard to completely detach yourself from a patient emotionally because you develop relationships with them,” she explains. “Acknowledging sad feelings after a patient dies is both normal and human.”

A Need for Teaching Coping Skills

Stories about how patient death impacts physicians are not uncommon, and they touch on grief and post-traumatic stress disorder. But articles about the impact of patient death on other healthcare professionals—such as pharmacists and nurses, many of whom tend to have more frequent and intimate patient contact—are not as common.

A study from 1987 found that 68% of pharmacy programs included some form of death education in their curricula; [Beall J, Broeseke A. Pharmacy students’ attitudes toward death and end-of-life care. Am J Pharm Educ. 2010 Aug 10;74(6):104]. However, that statistic pales in comparison to 95% and 96% of nursing and medical schools that included death training, respectively.

David Hays, PharmD, BCPS, FASHP, a clinical pharmacy specialist in emergency medicine at the University Medical Center of Southern Nevada, attributes the sparsity of dialogue surrounding the impact of patient death on pharmacists to the lack of training they receive as students.

However, he also believes the lack of death education in pharmacy training reflects the fluid climate of pharmacy practice and the industry dynamic shifting to more patient-centered care.

“As pharmacists, our roles have been evolving over the last 20 or so years to more bedside engagement,” Hays observes. “The traditional pharmacist didn’t do much bedside care.”

While current Accreditation Council for Pharmacy Education (ACPE) standards encourage patient-centered care and interdisciplinary practice, ACPE offers no explicit guidance regarding training in palliative care and the emotions surrounding patient death.

Coping Strategies

Hays says pharmacy schools should expose students to palliative care and end-of-life issues as early as possible in their curricula. Similarly, pharmacy residents can also benefit from training about death to learn coping skills for themselves and also to deal with bereaved family and friends.

Shuert recommends that practicing pharmacists take a moment to assess their emotional health following the loss of a patient. Some clinicians may find that exercising extra self-care or taking a day off can be cathartic.

“Above all, the pharmacist should reach out for support, whether from friends, coworkers, and family, or from a professional, if necessary,” Shuert says.

Hays took advantage of employer-provided counseling early on in his career—a service he has used regularly. After taking time to work through their emotions, Shuert advises pharmacists to resume their routines and a sense of normalcy as soon as possible.

Another critical element is setting healthy boundaries that allow pharmacists to grieve without becoming so emotionally invested that it limits their ability to practice. Seitzman-Siegel says pharmacists can find closure while setting boundaries so they can continue serving other patients.

For example, one of her colleagues sends sympathy cards to the patient’s family—an act that the pharmacist finds both courteous and therapeutic without being emotionally overwhelming. Saying a prayer or having sympathetic thoughts towards the patient and the family also allow pharmacists to manage their emotions in a healthy way.

In the oncology setting, Smith frequently uses humor to lighten the mood. Her team also makes a concerted effort to encourage a positive work culture by giving grieving colleagues small gifts such as pastries. Additionally, she finds keeping the goal of helping patients at front-of-mind makes the coping process less painful.

“Peer support is crucial to normalizing the experience for the affected team member, and reaffirming the individual’s competencies,” Shuert says. “This emotional support is a critical element to coping with the loss of a patient.”
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Pharmacy Education for the 21st Century

Schools increase focus on patients, outcomes, economics, and leadership in addition to products By Beth Longware Duff, contributing writer

As the role of today’s pharmacists expands beyond the counter and takes its place in the changing landscape of healthcare, the question arises: How well are pharmacy schools meeting their responsibility to prepare the next generation of pharmacists for the latest trends in the profession and industry?

Drug Topics sought the insights of a diverse group of individuals representing professional organizations, industry observers, experienced pharmacists, recent pharmacy school grads, and current students to get their take on the situation. The result is a snapshot of where pharmacy schools are today, along with some candid suggestions for ways they can better educate their students for the future.

Outcomes, EPAs, and Standards

How does a school of pharmacy guide its PharmD students in four short years to sufficiently help them find the areas of pharmacy that most interest them? Lucinda Maine, RPh, PhD, executive vice president and CEO of the American Association of Colleges of Pharmacy (AACP) says the challenge is one of both depth and breadth, due at least in part to the increasingly rapid pace of change in therapeutics.

"Schools of pharmacy can’t begin to believe that they can teach the students all the knowledge that they’re going to potentially access in their career," Maine says. She adds that the complexity of many therapeutic areas—and the complexity of being a successful researcher, manager, or leader—requires students to choose the path for which they have the greatest passion and drill into it.

"Unequivocally, every school should have faculty who are equipped to teach 21st century skills like informatics and pharmacogenomics at some basic level of exposure. And yet we know that there are likely not sufficient faculty resources to effectively address this at the right level across every curriculum," she adds.

In 2013, AACP published the latest iteration of its Center for the Advancement of Pharmacy Education (CAPE) Educational Outcomes, which are intended to provide a target toward which pharmacy curricula should be aimed. The current CAPE Outcomes focus on four specific areas: foundational knowledge, practice and care essentials, practice and care approach, and personal and professional development.

AACP recently offered additional curriculum guidance for pharmacy schools with its entrustable professional activities (EPAs) for new pharmacy graduates. Released in 2017 and patterned after a similar document for medical students entering residency, it identifies practices, procedures, and guidelines to
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assist faculties in developing students to their maximum potential. Validation of the 15 EPA statements was published late last year in the American Journal of Health-System Pharmacy.

The CAPE Outcomes were subsequently adopted by the Accreditation Council for Pharmacy Education (ACPE) as an integral part of its Standards 2016, which established the minimum standards that professional PharmD degree programs must meet to achieve and maintain accreditation. The standards focus on the required educational outcomes and their assessment, structural, and process-related elements necessary to implement evidence-based outcome measures that document achievement of the standards, and areas where programs can experiment and innovate within their curricula to meet the required CAPE Outcomes.

ACPE Executive Director Peter Vlasses, PharmD, says input from a consensus conference of accredited stakeholders—including pharmacy colleges and schools, professional pharmacy organizations, and student pharmacist organizations—greatly influenced the new standards. Two messages that came through loud and clear were that graduating students should be practice ready (able to directly contribute to patient care) and team ready (able to work in collaboration with other healthcare providers).

Vlasses notes that today’s pharmacy students spend 300 hours during their first three years of pharmacy school gathering practical experience in community and hospital pharmacies or in other available opportunities, such as industry.

“Basically, we heard that we need to make sure that students finish those three years and enter the fourth experiential year—the advanced pharmacy practice experience, or APPE—ready,” he explains. “They need to be actively engaged within the law and under the supervision of preceptors in the care of patients, and to apply the knowledge, skills, and abilities that they gained in the first three years in a controlled but active way so they get first-hand experience in doing the kinds of things they’ll be required to do on graduation.”

**Emphasis on Entrepreneurship**

The 2016 standards specifically mandate that entrepreneurship be taught in all pharmacy school curricula by 2019. It’s a move that’s applauded by George Zorich, CEO of ZEDpharma, and author of *Entrepreneurs in Pharmacy and Other Leaders*. He believes that existing core courses need to be adapted to make students more marketable when they graduate.

“Let’s get more entrepreneurs out there. If we do, we have a good chance of building businesses that create jobs and could benefit healthcare and society,” he says enthusiastically. “Let’s realize that big box retail will not be creating the same number of jobs in 2030 as they do today.”

Erin Albert, PharmD, JD, MBA, and senior director of education at the American Society of Consultant Pharmacists (ASCP), also advocates for curriculum expansions that emphasize leadership, entrepreneurship, and self-awareness.

“Most schools have electives in these areas, but few mandate these types of training,” she explains. “The irony is that we used to be almost all entrepreneurs, and we’ve done a 180 [degree turn] to being employees. But I’m starting to see the pendulum swing back the other way.”

Programs like the Master of Science in Pharmacy Business Administration (MSPBA) at the University of Pittsburgh School of Pharmacy are leading the way in that reversal. It offers core business fundamentals like financial accounting, financial management, and strategic management while also focusing on healthcare and the business of pharmacy. The program allows students to work full-time while going to school full-time.

“We’re looking for anybody working...
in the pharmacy sector of healthcare with at least two years’ experience,” says Bridget Regan, RPh, MBA, director of pharmacy business programs at Pitt. “We’re looking for somebody who wants to take on leadership roles within the industry or their current organization, be entrepreneurial, or look at other opportunities within healthcare to take on those skills and lead the changes that are happening.”

Twenty-one students have completed Pitt’s year-long MSPBA program since 2016, including recent grad Mark Thomas. After earning his PharmD in 2013 from Lake Erie College of Osteopathic Medicine, he joined a major pharmacy healthcare provider where he now works as a clinical advisor helping employers identify patterns in their drug spending. His work experience and the Pitt program opened his eyes to the business side of pharmacy, which he says was not part of his PharmD curriculum.

“The biggest deficit that we have right now in our profession is understanding and following the healthcare dollar. We’ve really lost sight of that because it has become pretty complex,” says Thomas. “Doing due diligence to understand how the healthcare dollar works is critical.”

**Changing the Curriculum**

Today’s pharmacy school students are tomorrow’s industry leaders. So what can the schools do to ensure that the future is secure and bright for both pharmacy and its practitioners?

Stephen J. Allen, RPh, MS, and retired CEO of the ASHP Research and Education Foundation, maintains that while schools do a solid job of preparing students to enter practice, their ability straight out of school is limited. He acknowledges that changing curriculum is a slow and deliberate process, particularly since the components are stipulated, evaluated, and accredited by ACPE.

Allen points to other challenges facing pharmacy academia like the availability of faculty to teach new subjects and an overabundance of schools that he predicts could glut the market and result in many unemployed pharmacists inside a decade. He proposes several subject areas that need additional focus, including verbal and written communication, healthcare economics, and niche pharmacy. As an example of the latter, he points to three programs that his alma mater, the University of Maryland School of Pharmacy, is developing to expose students to the fields of THC, communication, healthcare economics, and leadership.

“Students who are getting a PharmD degree must understand healthcare economics, and they must be able to lead,” he concludes. “If they want to be in a practice that can establish patient care plans, follow up and monitor a care plan, and collaborate as part of the interprofessional team, they have to show their value.”

ASCP’s Albert notes that savvy schools are hiring career coaches and experts in nontraditional pharmacy to share a wider bandwidth of experience. “But many faculty have only done hospital or community practice in their own careers, so it is critical for schools to hire professionals who have experience outside of these two settings,” she stresses. Other options that she says would be helpful for students are conferences on career alternatives, mentoring programs, and one-on-one career development counseling by trained professionals who have worked in a variety of settings.

Griffin Budde, president of the Class of 2020 at the University of Wisconsin School of Pharmacy, agrees that the curriculum should be as diverse as possible. Issues he’d like to see addressed include how automation and technology are going to affect pharmacy practice and the leadership role of pharmacists.

“Pharmacy schools are preparing their students well when it comes to hard science, but I believe there is room to improve in areas of entrepreneurship and critical outside-the-box thinking,” he adds. “The ability to get people to buy into you is not an easy one to train, and I don’t know if it can fit into a curriculum, but I do think that’s the kind of skill we need.”

**The Last Word**

ACPE’s Vlasses says declining enrollments, more competition for job openings, and cutbacks in state investment in education are major challenges facing the profession as a whole and pharmacy schools and their students specifically.

“The crux of the change of pharmacy education is moving from product orientation to patient plus product, but even more than that to chronic disease management and preventative care,” he concludes. “The approach to the patient is one where you have to be a problem solver, you have to be able to educate audiences, and you have to be an advocate for your patients’ best interests. This whole interprofessional collaboration is the future.”
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Pharmacists Want More Time with Patients

Survey shows pharmacists are eager to provide care for the whole patient continuum  
By Fred Gebhart, contributing writer

The typical pharmacist gets to spend just 10% of their working day with patients, but they want to spend exponentially more time with them; up to 74% of their time for chain pharmacists and 60% for health system and specialty pharmacists.

That is the key take away from the first-ever Pharmacy Check-Up survey sponsored by AmerisourceBergen. This nationwide survey across practice settings found that all pharmacists expect to spend significantly more time on patient-focused activities in the next five years.

Patients visit a pharmacy an average 35 times per year compared to just four visits to see medical providers. The potential is there to expand pharmacists’ role in providing direct patient care, but turning that potential into practice will take major changes in healthcare delivery systems.

“We are at a pivotal place in our profession,” says Matthew Wolf, PharmD, Group Vice President, Consulting Practice, at AmerisourceBergen’s Pharmacy Healthcare Solutions. “We have got to get better at getting a seat at the table in the C suite so leaders understand the importance of who we are and what we do. We have to help other players in healthcare understand the importance of who we are and what we can do. Pharmacy is shifting away from being a cost center, especially in the health system and specialty worlds, to becoming a revenue center. The closer we get to the patient, the more time we can spend with patients, the more we can affect their health outcomes. That is particularly important as we move away from fee for service to fee for value.”

The move toward pay for performance is an important opportunity for pharmacists, Wolf says. While he focuses on the evolving role of pharmacists and pharmacy services in health systems, the same need to demonstrate value and improved outcomes is also playing out in chain and independent pharmacy.

The barriers to expanding patient contact time depend on the practice setting. Chain pharmacists must deal with staffing limitations and insurance reimbursement issues. They need more time to deliver the level of care they have been trained to provide and want to provide.

“Too much focus is being placed on number and patient care is suffering. Staffing is being decreased while the workload is increasing.”

Independent pharmacists must deal with reimbursement issues as well as with payer and manufacturer contracting complications.

“As reimbursement declines and cost continues to increase, the only thing we can do to stay afloat is reduce labor. And when you reduce labor, it affects patient care,” said one independent pharmacist.

On the health system side, pharmacy has long been viewed as a cost center. That began to change a decade ago as changes in reimbursement across different care settings encouraged hospitals to focus on ambulatory clinics and ambulatory pharmacy. More recently, the focus has shifted to specialty pharmacy. What hasn’t changed is the potential impact pharmacists can have on metrics such as readmissions as well as on the bottom line.

Take discharge planning and counseling: In an era when more than half of hospital readmissions are linked to some sort of adverse drug event, the need for pharmacist involvement in discharge planning is greater than ever. Where the financial rewards of healthcare were once focused on dealing with acute events through physician visits, hospital admissions, and urgent prescriptions, financial rewards going forward are focused on preventing acute events: fewer admissions, fewer readmissions, fewer acute scripts, more preventative care, more chronic medications.

“We need, as a profession, to stop looking at ourselves as inpatient pharmacists or outpatient pharmacists,” Wolf said. “We are pharmacists. As care is shifting from the inpatient hospital to ambulatory, we are all shifting to more of a quality-driven perspective, keeping the patient out of the hospital by keeping them well. That changes the paradigm for pharmacists. We have to care for the whole patient continuum rather than just ‘I’m a pharmacist who supports a patient while they are in the hospital’ or ‘I support patients in the ambulatory setting’. Our new paradigm is ‘I support the patient, period.’”
In October 2018, the FDA approved baloxavir marboxil (Xofluza) for treatment of acute, uncomplicated influenza in people age 12 years and older who have had symptoms for no more than 48 hours. Antiviral drugs can reduce symptoms and duration of the flu when administered within 48 hours of onset. Due to potential resistance of flu viruses to antiviral medications, it is beneficial to have treatment options that have different mechanisms of action.

Baloxavir marboxil is a polymerase acidic endonuclease inhibitor with demonstrated efficacy in treating influenza A and B virus infections in preclinical models, notably against strains resistant to current antiviral agents.

**Efficacy**

Baloxavir marboxil was evaluated in two randomized double-blind placebo-controlled trials conducted in Japan and the United States during two different flu seasons. In the phase 2 placebo-controlled trial, median time to alleviation of symptoms was significantly shorter for all doses of baloxavir marboxil (54.2 hours in the 10-mg group, 51.0 hours in the 20-mg group, and 49.5 hours in the 40-mg group) compared to placebo (77.7 hours).

Baloxavir marboxil at all three doses had significantly greater reductions in influenza virus titers on days 2 and 3 versus placebo.

The phase 3 trial reiterated that baloxavir marboxil significantly reduced the median time to alleviation of influenza symptoms compared to placebo. The difference in time to alleviation of symptoms was greater in patients who initiated antiviral therapy in less than 24 hours versus more than 24 hours after symptom onset. This trial also demonstrated that baloxavir marboxil was superior to both placebo and oseltamivir in antiviral activity. No difference in the time to alleviation of symptoms between the baloxavir marboxil group and the oseltamivir group was identified.

It is important to consider limitations of use in antiviral therapies. Influenza viruses evolve over time, and various factors such as the specific type of virus or resistance patterns can lead to diminished clinical benefit and efficacy of antiviral drugs.

**Safety**

There were no apparent safety concerns associated with the use of baloxavir marboxil. The most common adverse drug reactions associated with this drug include diarrhea (3%), bronchitis (2%), nausea (1%), nasopharyngitis (1%), and headache (1%). In the phase 3 trial, adverse events were reported in 20.7% of patients receiving baloxavir marboxil, 24.6% of patients receiving placebo, and 24.8% of patients receiving oseltamivir.

Safety has not been evaluated in patients under 12 years of age or who weigh less than 40 kg.

**Dosing**

Baloxavir marboxil is available as a 20-mg or 40-mg oral tablet. In patients weighing 40 kg to less than 80 kg, a single oral dose of 40 mg is recommended. In patients weighing 80 kg or more, a single oral dose of 80 mg is recommended.

Baloxavir marboxil should be taken within 48 hours of influenza symptom onset and can be taken with or without food. It should not be administered with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids, or oral supplements such as calcium, iron, magnesium, selenium, or zinc, as coadministration may decrease plasma concentrations of baloxavir marboxil.

Concurrent use of baloxavir marboxil with intranasal live attenuated influenza vaccine has not been evaluated but may decrease the effectiveness of the vaccine due to inhibition of viral replication by baloxavir marboxil.

There were no clinically meaningful effects on renal or hepatic function associated with the use of baloxavir marboxil. The pharmacokinetics in patients with severe renal or hepatic dysfunction have not been evaluated.
Change Is Like a Hemorrhoidectomy

My Dad was a top welder at a paper mill. He had an amazing work ethic and was one of the many tough guys from America's greatest generation. He served his country for four years in World War II. In May of 1986, he performed his toughest job, giving his only daughter, my sister Mary, away in marriage.

One of his nephews asked him, "How do you feel about this day?" My Dad smiled and said, "It is like a hemorrhoidectomy—uncomfortable at first, but after a while, it will feel so good."

Change is an inevitable part of life. Our jobs change, our families change, our kids change, and whether we realize it or not, we change. Thirty-seven years of working with patients and staff has given me a different outlook. The kids are all successful, the house is paid for, and when we get our paychecks deposited into the bank, the money actually stays there! Some changes are very good.

Our profession has changed; it didn’t happen all at once, but there are definitely some highlights that have driven the changes I’ve experienced since 1981. The computerization of the pharmacy in the '80s, electronic claims submissions of the '90s, Medicare D in 2006, and then the Affordable Care Act. Early in my career the drudgery was filling out triplicate claim forms for insurance companies. One of my old pharmacist colleagues said back in 1990, "Young man, when you let those black boxes [modems] in your pharmacy, you can kiss your profession good-bye." Could you possibly imagine running a pharmacy without internet access? Insurance companies bring their own challenges, and our profession had to adapt back in the 1990s. We do a whole lot more with a whole lot less.

The biggest change I’ve seen in my career is the almost exponential growth in salaries. In 1981, I started at $12.35 an hour, which was $2 an hour more than my dad. Today, my dad would be making $25 an hour. Do we know any pharmacists making $27 an hour? The "golden handcuffs" have kept many of us in less-than-optimal jobs because the paycheck is fabulous.

Be Open to Opportunity

After 25 years in the same local chain, my wife, Denise, was offered an opportunity to open and manage a retail pharmacy in a health system. There was great comfort in what she had been doing for 25 years; she knew her patients and staff well, but didn’t want to pass on this opportunity. To the amazement of everyone (including her husband) she signed on with the health system and did an excellent job. Four years ago, Denise was asked if she knew a pharmacist who might be interested in a clinical opportunity: a paid position with Center Volunteers in Medicine (CVIM), which takes care of the underserved.

Denise took that job and now works 18 hours a week with CVIM and one day a week at the health system. She does intense patient counseling at CVIM, where she got life-sustaining drugs for a patient from overseas, started a patient who only spoke Russian on Lantus, and has helped several Hispanic people with minimal English-speaking abilities. She coordinates hospital discharge med lists with drugs she can get free for patients. She makes a huge impact on every patient who walks into that clinic, along with the physicians who volunteer there. She has one of the most rewarding careers of any pharmacist I know. She has taken in stride the changes in this profession much to her benefit.

Today, everyone worries about market saturation of pharmacists and the availability of jobs. Talking to health system pharmacist managers, I’ve learned there are plenty of pharmacist positions they have trouble filling.

Remember: Your license hangs on the wall by a nail. Go find a nail that will make you and your license happy. It will be “uncomfortable at first, but after a while, it will feel so good.”

“Our jobs change, our families change, our kids change, and whether or not we realize it, we change.”

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