Take the omega-3 challenge!

Professional organizations such as the American Diabetes Association, American Society of Health-System Pharmacists, and American Association of Clinical Endocrinologists do not recommend fish oil dietary supplements to treat disease.  

<table>
<thead>
<tr>
<th>Question</th>
<th>True?</th>
<th>False?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fish oil dietary supplements are free of contaminants, such as toxins and oxidized (rancid) lipids.</td>
<td></td>
<td></td>
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<tr>
<td>Fish oil dietary supplements may commonly contain lower amounts of omega-3s, like EPA and DHA, than advertised on the label.</td>
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<tr>
<td>Fish oil dietary supplements, which are regulated as food, have FDA pre-approval and purity requirements.</td>
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<tr>
<td>Because fish oil dietary supplements may contain one-third or more saturated fat in each capsule, to try to achieve the 4-g daily dose of EPA found in VASCEPA®, a prescription drug, one would need to consume 10 to 30 fish oil capsules containing saturated fat that could equal or exceed that of a cheeseburger.</td>
<td></td>
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</tbody>
</table>

Fish oil dietary supplements are not interchangeable with VASCEPA, a prescription drug.

Check your answers below, then visit vascepahcp.com/PharmQuiz for more.

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.

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

IMPORTANT SAFETY INFORMATION FOR VASCEPA

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components
- Use with caution in patients with known hypersensitivity to fish and/or shellfish
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy
- 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

Please see accompanying Brief Summary of full Prescribing Information or go to www.vascepahcp.com.

References:
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.

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
• 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 reactions observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Adverse reactions reported in at least 2% and at a greater rate than placebo for patients treated with VASCEPA based on pooled data across two clinical studies are listed in Table 1.

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

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

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

An additional adverse reaction from clinical studies was oropharyngeal pain.

7 DRUG INTERACTIONS

7.1 Antiplatelet Agents

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 treatment 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/kg/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/kg/day based on body surface area comparison.

In a multidrug 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 ≥0.3 g/kg/day at human systemic exposure following an oral dose of 4 g/kg/day based on body surface area comparisons across species. Additional variations consisting of early incisor eruption and increased percent cervical ribs were observed at the same exposures. Pups from high dose treated dams exhibited decreased copulation rates, delayed estrus, decreased implantations and decreased surviving fetuses (F2) suggesting multigenerational effects of ethyl-EPA at 7 times human systemic exposure following 4 g/kg/day 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/kg/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 ‘C’-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.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year rat carcinogenicity study with oral gavage doses of 0.09, 0.27, and 0.91 g/kg/day icosapent ethyl, respectively, males did not exhibit drug-related neoplasms. Hemangiommas and hemangiosarcomas of the mesenteric lymph node, the site of drug absorption, were observed in females at clinically relevant exposures based on body surface area comparisons across species relative to the maximum clinical dose of 4 g/day. Overall incidence of hemangiommas and hemangiosarcomas 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 fecal 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 with and without metabolic activation.

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

Distributed by: Amarin Pharma Inc., Bedminster, NJ, USA
Manufactured for: Amarin Pharmaceuticals Ireland Limited, Dublin, Ireland
Amarin Pharma Inc. Bedminster, NJ 07921
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Voice of the Pharmacist

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Drug Topics | AUGUST 2018 | DRUGTOPICS.COM
I’ve been thinking about mulligans and cocktails—drink cocktails mixed, shaken, stirred, poured, and drug “cocktails” admixed and compounded in hospital pharmacy cleanrooms.

Watching a bartender in the Cayman Islands exercise his craft, I asked, “How do you ensure combining the right amount of each ingredient? Do you ever make mistakes?” To which he replied, “All the time.”

I asked about direct pours, the durations of which seem to be calculated by muscle memory and mental counts. “After a while, you just know,” he said, while adding splashes and pinches of this and that to his concoctions.

As for quality assurance, he explained the “straw test,” where mixologists verify that they haven’t forgotten anything nor added too much or too little of any ingredient by tasting a tiny sample of the drink on the end of a straw.

The Other Kind of Cocktails

It’s easy to see why IV medications, prescribed by physicians, prepared in pharmacy clean rooms, and administered by nurses to patients, are sometimes referred to as “cocktails.” It’s also easy to see why it’s so much more important to get the recipe right in medicine. A poorly mixed cocktail can leave a bad taste in your mouth, a poorly mixed medication can lead to much worse.

Of course, no one would intentionally combine the wrong ingredients or incorrect volumes. However, even the best trained, most conscientious, and least distracted preparers make mistakes.

The best observational study to date, reveals that just over 9% of preparations involve one or more errors. The most frequent have to do with incorrect volumes, followed by wrong ingredients.

Hats off to those hospitals that have the courage to admit their pharmacies are vulnerable. Kudos to those who have implemented technologies proven to prevent or intercept mishaps.

Work Flow Technology

Rather than handing technicians a stack of printed medication orders or worse, preprinted labels, IV work flow systems provide technicians with on-screen orders, one at a time. Software check lists guide preparers, step-by-step, through pharmacy-reviewed “recipes.” Barcodes on delivery containers are scanned to verify that the right items have been selected. If not, software prevents moving to the next step. In sequence, technicians continue scanning listed ingredients to be added to containers, again allowing them to proceed only when verified.

These technologies also use volume-verification processes, the most accurate of which is gravimetrics. Preparers are required to weigh ingredients in order to verify that the correct amounts have been drawn and/or injected. If the results don’t match the recipe, the system won’t produce a label. Once everything is correctly filled, a barcoded label is printed and applied for scanning at the point of infusion—ensuring the right patient receives the right IV.

I argue that every hospital should provide its pharmacy technicians with work flow software that incorporates product- and volume-verification features—making it easier for them to get orders right and harder to get them wrong.

In the Caymans, I ordered a snappy ginger-infused lemonade with soda water and a sprig of mint. My first sip revealed the frosted glass contained wrong amounts of the right ingredients, which could have been caught by the bartender with a straw test. I gave the guy a mulligan and he got things right on the second try.

No harm. No foul. Plus a complimentary drink.

REFERENCE

POLICY CHANGES

Big changes are coming to pharmacy. Read about what policy issues will impact you.

10

FROM THE BOARD
Preventing Med Errors
PAGE 3

SMALL DOSES
Prescription Kiosks
PAGE 6

PHARMACY PRACTICE
Drug Pricing Tools
PAGE 17

CLINICAL PRACTICE
Pharmacists’ Role in HIV
PAGE 22

CAREER
Cardiology Pharmacy
PAGE 24

TECHNOLOGY
Virtual Staff Tool
PAGE 30
Hospitals and the Department of Defense have endorsed kiosks as a convenient way for patients to pick up prescriptions. Retail pharmacies are starting to recognize their value too.

Interest from major retail chains has picked up in the past two months or so, says Linda Pinney, founder and CEO of Asteres, which has delivered more than two million prescriptions via its ScriptCenter kiosks.

"Stores are looking at all these various ways to improve their traffic - such as curbside pickup - because foot traffic is dropping at the front of the store. The advent of home delivery services like Amazon, PeaPod, and DoorDash is hurting foot traffic at all types of stores, including supermarkets and drug store chains," Pinney tells Drug Topics.

Asteres, which has hundreds of kiosks in healthcare systems, military bases, and Veterans Administration facilities, is now in talks with several major retail chains, according to Pinney.

ScriptCenter kiosks differ from Express Scripts and MedAvail’s new MedCenter prescription kiosks because they are operated by the pharmacies themselves and are not considered a dispensary. They simply serve as a pickup point for prescription—and a convenient service that could draw in new pharmacy customers. “We are not replacing the pharmacy; we are an extension of the pharmacist. The pharmacy fills it as usual and ScriptCenter is a pickup place,” Pinney says.

MedCenter kiosks, meanwhile, can safely and securely dispense chronic, acute, and OTC medications under the supervision of licensed pharmacists, and are compatible with both handwritten and electronic prescriptions, according to Express Scripts.

ScriptCenter and MedCenter kiosks have pharmacists available via video or phone calls. Patients at the kiosk can press a button and conduct a video chat with a pharmacist.

Asteres has grown three-fold or four-fold in the last three years. “We have taken our time to go after branded hospitals, such as Cleveland Clinic and Johns Hopkins. Now that the concept is being proven and it has a good value, it is starting to take off,” Pinney says.

Also, more state boards of pharmacy are allowing the kiosks because they realize that “you need alternate access points,” Pinney says. “Thirty percent of discharge scripts are not picked up due to not having access. Convenience equals compliance.”
PCC Shortages Worry ER Pharmacists

Emergency department pharmacists have become increasingly concerned about shortages of prothrombin complex concentrate (PCC) (Kcentra, CSL Behring GmbH), ASHP says.

PCC is indicated before urgent surgery or during acute major bleeding to replace some of the blood coagulation factors in patients being treated with warfarin or other vitamin K antagonists.

“We have a very small number of vials left,” Krysta Baack, PharmD, BCPS, ED pharmacist at Nebraska Medicine—Nebraska Medical Center in Omaha, NE, tells ASHP in a press release. CSL Behring issued an urgent recall of three lots of Kcentra in March after a manufacturing change resulted in an increased risk of vial breakage during transport and handling of the product. In addition, ASHP’s May 16 drug shortage bulletin stated that the manufacturer had “short-term delays in product releases” and insufficient stock for “usual ordering.”

Amie Quinones, ED pharmacist for Intermountain Medical Center in Murray, UT, tells ASHP, in a statement, that the PCC shortage forces clinicians to deviate from evidence-based practices that are the standard of care. “We have alternatives, but there’s no literature [support] for those alternatives,” Quinones says.

Drug Errors Not Common, Consumer Group Says

A consumer advocacy group set out to collect information about drug dispensing errors, and so far has found relatively few. “We are now urging persons to call us anytime at 866-714-6466 if their local pharmacy provided them with someone else’s prescription or the wrong prescription or the wrong dose,’” a recent statement from U.S. Drug Watchdog states. “For some people, the outcome of receiving the wrong prescription or a prescription with the wrong drugs or incorrect dosage, a recent statement from U.S. Drug Watchdog states. “For some people, the outcome of receiving the wrong prescription or a prescription with the wrong drugs or incorrect dosage could be fatal. We would like to help you get compensated.”

Since issuing the statement, Michael Thomas Martin, president of U.S. Drug Watchdog, says the organization has only received calls from two consumers who experienced minor drug errors. Both were cases of the wrong dosage for minor pain medication after dental procedures, and were not egregious or dangerous errors, Martin says.

“We expected to hear from customers of Walmart, Rite Aid, and other major chains about mistakes, but we didn’t get anything,” Martin says. “We are impressed. When you think of long pharmacy lines and drive up windows, people get cranky. We haven’t had any of those people call and say, ‘I’ve gotten the wrong prescription or the wrong dose.’”

U.S. Drug Watchdog decided to issue the call for patients to contact it about errors after an unnamed “credible pharmacy business insider” urged the group to look into the problem, which that person said was widespread—particularly at busy drug store chains with long lines of customers, says Martin. The unnamed insider said that a lot of errors were being made by compounding pharmacies as well. Drug Topics asked for the name of the business insider, but Martin would not provide it.

U.S. Drug Watchdog is a consumer advocacy group that sometimes works with attorneys in cases where drugs and devices have caused serious side effects. However, the group is not typically involved in class action lawsuits, because “we don’t necessarily believe consumers are well-served by these lawyers,” Martin says.
DEA May Issue Limits on Opioid Production

A new regulation from the DEA states that if the agency believes a particular opioid or a company’s prescription painkillers are being diverted for misuse, it can reduce the amount that is allowed to be produced in a given year.

“These common-sense actions directly respond to the national opioid epidemic by allowing DEA to use drug diversion as a basis to evaluate whether a drug’s production should be reduced,” says DEA acting administrator Uttam Dhillon. “This also opens the door for increased communication and better information sharing between DEA and individual states, as we work together to address the opioid problem plaguing our country.”

The revised limits will “encourage vigilance on the part of opioid manufacturers, help DEA respond to the changing drug threat environment, and protect the American people from potentially addictive drugs while ensuring that the country has enough opioids for genuine medical, scientific, research and industrial needs,” DEA says in a statement.

Blood Pressure Drug Could Help Diabetics

For the first time, an inexpensive blood pressure drug has been shown to ease the symptoms of Type 1 diabetes.

Verapamil (Calan, Verelan) was associated with a lower increase in insulin requirements, on-target glycemic control, fewer hypoglycemic events, and an improved mixed-meal-stimulated C-peptide area under the curve, a measure of endogenous beta cell function, researchers say in the study published in Nature Medicine.

“Addition of once-daily oral verapamil may be a safe and effective novel approach to promote endogenous beta cell function and reduce insulin requirements and hypoglycemic episodes in adult individuals with recent-onset T1D,” the University of Alabama researchers write.

Verapamil, an antihypertensive calcium-channel blocker, may work because it protects some of the pancreatic cells that are damaged, allowing them to continue producing a little insulin, according to the researchers.

“This will have to be proven in a larger population and also in other age groups. We also would like to extend it to children,” Anath Shalev, MD, director of the diabetes center at the University of Alabama, tells NBC News.

The researchers also previously found that verapamil promotes the survival of insulin-producing beta cells and reverses diabetes in mouse models.

CDC Issues Fentanyl Alert

Overdose deaths from fentanyl and fentanyl analogs are on the rise, CDC’s Health Alert Network says.

“The dramatic rise in the supply of illicitly manufactured fentanyl and fentanyl analogs has been mirrored by an equally dramatic rise in deaths involving synthetic opioids other than methadone, a category which includes fentanyl and fentanyl analogs,” says the alert.

Synthetic opioid overdose deaths in the U.S. rose from 3.1 to 6.2 deaths per 100,000 between 2015 and 2016, marking the first year that synthetic opioids became the most common type of opioid involved in all opioid overdose deaths. Preliminary data from the National Center for Health Statistics finds that more than 55% of opioid overdose deaths occurring nationally in the 12-months ending November 2017 involved synthetic opioids, accounting for more than 27,000 overdose deaths.

“This 12-month sum of synthetic opioid overdose deaths exceeds the total number of all opioid overdose deaths in 2013, when deaths involving synthetic opioids first began to climb,” the CDC says.

From January through June 2017, the National Forensic Laboratory Information System received an increased number of drug submission reports from state and local forensic laboratories of fentanyl analogs and other synthetic illicit opioids. For instance, carfentanil, 100 times more potent than fentanyl, rapidly increased from an estimated 1,251 submissions in 2016 to 2,268 during the first six months of 2017, the system reports.

Christine Blank is a contributing editor.
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Policy Changes Coming to Pharmacies

What you need to know

Valerie DeBenedette

Here’s a sentence that has been true for millennia: Change is coming. In pharmacy, for the next six months to two years, this could be truer than ever as laws and regulations come into effect that could benefit the profession. Some expected changes have been long sought for, while others are of more recent vintage. Many will come through new or modified state and federal legislation or regulations.

But what policy changes might be nearer rather than further off and how will they affect the practice of pharmacy? We’ve narrowed it down to four areas of change and then asked some experts what to expect.

1. PBM Transparency Rule Changes
Pharmacists have been complaining for a long time that PBMs do not reimburse them fairly, and state legislatures are starting to take notice, says Allie Jo Shipman, PharmD, MBA, associate director for state government affairs at NCPA.

Many states have passed legislation related to transparency on the part of PBMs. Fair pharmacy audit legislation, which allows state regulatory agencies to audit PBMs for information on what drugs cost compared to the reimbursement to pharmacies, has passed in about 40 states, Shipman notes. Greater transparency would help retail pharmacies understand reimbursement policies and rates. “One big trend that we saw come up this year especially is trends in transparency and disclosure reporting, especially for state Medicaid agencies.”

Kentucky, Georgia, and Louisiana are among states that are requiring PBMs to release information on drug pricing and reimbursement rates to pharmacies as it relates to Medicaid or other state health benefit plans.

One catalyst triggering lawmakers to act on PBM transparency was CVS Caremark’s move last year to cut reimbursement rates for drugs in several states, Shipman says. “It is finally starting to come to a head where state legislators have been hearing from pharmacists and from [pharmacy] associations about PBMs and these practices,” she says.

Arkansas is the first state to pass a law to fully authorize its insurance commissioner to regulate PBMs. The law permits the state insurance commissioner to review and approve PBM compensation programs to ensure that reimbursement for prescriptions is fair and...
reasonable, says Jason Rapert, a Republican state senator in Arkansas, who is also president of the National Council of Insurance Legislators. The council, made up primarily of state legislators, creates model versions of laws that can be used to draft legislation. The organization has drafted a template, “Pharmacy Benefits Manager Licensure and Regulation Model Act,” that states can tailor to their needs. The draft and comments can be read at https://bit.ly/2A8arwT.

“[PBMs] have been getting away with making up their own rules, playing their own version of street ball here, and nobody’s calling foul,” says Rapert. “We need a referee that can actually operate in this arena,” he tells Drug Topics. The goal of the law is to “pull back the curtain” and see what is going on in PBMs, he says. Pharmacists across the country, who have commented on the draft.

Giving states more oversight to PBM operations does not always require new legislation, Shipman notes. Some states, like Pennsylvania and Montana, are having their auditors general look more closely at PBMs, she says. “Even if they haven’t passed legislation, they are still looking at PBMs with greater scrutiny.”

2. DIR Fee Changes
Direct and indirect reimbursement (DIR) fees and PBMs are interconnected, says Kala Shankle, JD, NCPA’s director of policy and regulatory affairs. These fees, used by PBMs in Medicare Part D, can be any retroactive fee. Many are based on quality-based metrics, but it is not clear what those metrics are measuring, she says. “The DIR fight is largely a Medicare fight and independent pharmacists are flat-out angry about DIR fees because something like 35% to 36% of a typical independent’s business will be Medicare patients.”

Knowing what metrics PBMs are using to base reimbursement would help allow pharmacists to control costs and reduce the risk of being reimbursed less than what a drug cost months after a prescription was filled.

A bill has been proposed in the House—HR 5958, “Phiar Pricing Act of 2018”—which seeks to clarify the metrics used to determine DIR fees, Shankle says. Bills similar to this one have been proposed in previous Congresses.

3. Provider Status Changes
Expanding the scope of practice for pharmacists is being considered in state legislatures and in Congress. Drug Topics Editorial Advisor David D. Pope, PharmD, CDE, chief of innovation and founder of Strand, a company that helps pharmacists launch clinical services within their communities, says momentum is building to let pharmacists practice at the top of their license. This is particularly true in states with large areas that are underserved. Some rural counties in the United States have no physicians and hospitals that are hours away.

In Congress, a main consideration is whether Medicare should cover payments to pharmacists in these underserved areas, notes Drug Topics Editorial Advisor James A. Jorgenson, RPh, MS, FASHP, CEO of Visante, a company that consults on healthcare optimization and high-performance pharmacy development. “Nationally, more than half of the 100 total members in the U.S. Senate have signed on to support the Pharmacy and Medically Underserved Areas Enhancement Act [S 109],” he says. “With 51 cosponsors, the bill has surpassed the number of votes necessary to pass this legislation in the Senate.” The same bill is HR 592 in the House of Representatives, he notes.

The bill would provide for Medicare coverage and payment for certain pharmacist services that are furnished by a pharmacist in a health-professional shortage area, and that would otherwise be covered under Medicare if furnished by a physician. Allowing pharmacists to do more in rural areas that are underserved is significant, Pope says. The U.S. Census defines what constitutes a rural area, and a large part of the country falls under that designation.

On the state level, many are considering allowing pharmacists to prescribe oral contraceptives, while others would allow them to prescribe treatments for flu or strep throat, Pope says. Virginia is considering allowing pharmacists to perform opioid abuse counseling. Penn-
sylvania is discussing allowing pharmacists to counsel for tobacco cessation. These kind of scope-of-practice expansions add up, he says. For example, allowing pharmacists to counsel patients about diabetes, another practice being considered, would mean that they could conceivably be counseling almost one third of U.S. adults.

The APhA had been promoting increased scope of practice for a long time, Pope notes. The organization even has a website specifically to promote the idea: Pharmacistsprovidecare.com.

“APhA supports state pharmacy associations’ efforts to expand state scope of practice which has experienced significant success in recent years,” says Stacie S. Maass, BSPharm, JD, APhA’s senior vice president for pharmacy practice and government affairs. Changing provider status is complicated, she tells Drug Topics. “It is dependent on a complicated combination of policies involving payment, scope of practice and payers, and governments authorizing who can provide the service.”

As the scope of practice for pharmacists increases, reimbursement for these activities should become widespread, because expanding what a pharmacist can do is in the best interests of all healthcare stakeholders, says Jorgenson. “The fastest growing expense line in healthcare is medicine, and who has more education and ability to impact that than pharmacists?”

Health insurers are starting to recognize that adding a pharmacist to clinics and to care teams helps lower costs, he says, noting the work done to do that by Blue Cross Blue Shield of Michigan and the University of Michigan healthcare system, which has led to lower healthcare costs. (For more, visit bit.ly/2uAod68.)

Maass says expansion of scope of practice does not ensure there will be increases in payments, but it might. The need for increased healthcare access, the push toward value, and the recognition

**HR 5958: KEY CLAUSES**

- Prices negotiated with pharmacy at point-of-sale
  Subject to subclause (iii), for plan years beginning on or after January 1, 2019, negotiated prices for covered part D drugs described in clause (i) provided under a prescription drug plan, including all pharmacy price concessions and all incentive payments and adjustments negotiated with the pharmacy dispensing such drug, shall be provided at the point-of-sale of the covered part D drug. If the negotiated price of such drug, including all pharmacy price concessions and all incentive payments and adjustments negotiated with such pharmacy, is not possible to calculate at the point-of-sale, the PDP sponsor of such plan shall use an estimated negotiated price, including all estimated pharmacy negotiated price concessions and incentive payments and adjustments and taking into account the negotiated price of such drug in the prior year (if available).

- Application of incentive payments and adjustments
  For plan years beginning on or after January 1, 2019, in the case that a PDP sponsor uses incentive payments and adjustments with respect to payment to a pharmacy for a covered part D drug, such payments and adjustments shall be determined through the use of a quality measure approved by the Secretary and established by the working group established under clause (iii).

- No increase in cost sharing
  Subclause (i) shall not apply in the case where application of such subclause would increase the amount owed by an individual in cost sharing above the amount such individual would have owed in cost sharing without application of such subclause.

- Discrepancies between negotiated prices and actual reimbursement
  In the case that the Secretary determines that the negotiated price of a PDP sponsor applied at the point-of-sale with respect to a covered part D drug for a year dispensed by a pharmacy was not equal to the total reimbursement made to such pharmacy for such drug for such year (taking into account any incentive payments and adjustments and pharmacy price concessions, regardless of when such payments and adjustments or price concessions were applied), such sponsor shall, not later than 90 days after receiving notice of such determination, furnish to the pharmacy that dispensed such drug and to the Secretary a written explanation of why such negotiated price was not equal to such reimbursement.
of the positive impact pharmacists have on patient outcomes and costs, is leading to an increase in payment to pharmacists for their services beyond those related to dispensing, she says.

While it would be nice to have changes to provider status made in one fell swoop nationally, incremental change at the state level is what more commonly happens, Pope says. “If we are going to move the landscape, it is going to happen bits at a time.”

4. Compounding Changes

Changes to the policies for compounding pharmacies are on their way, both in standards issued by the United States Pharmacopeia—National Formulary (USP) and in the oversight of these facilities by the FDA and state boards, says Gus Bassani, PharmD, vice president of research and development at PCCA, a supplier of ingredients, excipients, and technical consulting for pharmacies, healthcare missions, and outsourcing facilities.

For USP, the sections that are undergoing changes are chapters <795> and <797>, Bassani says. USP <797> covers sterile compounding and USP <795> concerns nonsterile compounding. Both chapters govern how pharmacies compound products and have an impact on specialty pharmacies.

The goal is to have chapters <795> and <797> become official by December 2019, Bassani says. Implementation of chapter <800>, which concerns handling of hazardous drugs and ingredients, was held up so that facilities that conduct this kind of compounding could make necessary changes to infrastructure to stay in compliance.

Although USP sets standards for how compounding should be conducted, the chapters are only standards, not regulations, Bassani says. State boards of pharmacy may decide not to require their full implementation, depending on their own needs. “You could have a very rural state that may have some unique needs as it relates to their population and patient access issues versus other states,” he says. “There’s some good reasons why states may want to do their own thing, but overall the standards are good for patient safety.”

On the national regulatory side, the FDA regulates outsourcing pharmacies mainly through section 503B and determines what bulk drug substances pharmacies can use in compounding through section 503A, Bassani notes. The FDA has been issuing guidance documents to clarify some of the rules, he says. For example, 503A facilities are not supposed to create a copy of a commercially available product; the FDA generated guidance documents on what constitutes a copy, along with other guidelines, he says.

The FDA appears to want to increase the number of facilities that operate under 503B, Bassani tells Drug Topics. “They have stated their intent is to issue new regulations and guidance around the good manufacturing practices that would be required of an outsourcing facility. Currently they’re required to comply with full CGMP [current good manufacturing practice], just like a big pharmaceutical manufacturer. But it’s our sense that the FDA would like to see more pharmacies, more compounders registering as 503Bs. But it is millions of dollars of investment to do that,” he says. “Their intent, as we understand it, is to make it a little bit more appealing for compounders to become federally registered outsourcing facilities.”

A bill in the House of Representa-

PBM have been getting away with making up their own rules, playing their own version of streetball here, and nobody’s calling foul.”

Are Changes Certain?

If some new laws and regulations are always to be expected, what cannot be predicted is when and to what extent things will change. Bills can get stalled in state legislatures. Regulations may get put through more comment periods or placed on hold.

Change may come, but it is not inevitable, says Jorgenson. “I think if we don’t get these types of changes in maybe the next three to five years, it is going to be difficult to ever get them done to a level we would like to see done. That window of opportunity is not going to stay open forever.”

Valerie DeBenedette is managing editor of Drug Topics.
As the summer winds down, pharmacists need to gear up for students returning to school in September. Ensuring that children have the right medications for attention deficit hyperactivity disorder (ADHD) is a top priority.

More than 5 million children have an ADHD diagnosis, according to the 2016 National Survey of Children’s Health, a parent-focused survey conducted by the U.S. Census Bureau on behalf of HHS. Included in the total are 2.2 million children aged 6 to 11 and 2.9 million adolescents aged 12 to 17. Two out of three of children who are diagnosed take a medication (62%), and nearly one out of three receive a combination of medication and behavioral treatment (32%).

Many families don’t notice ADHD symptoms as much in the summer, when children are very active, and often they will lapse on medications, says Jake Olson, PharmD, owner of Skywalk Children’s Pharmacy in Milwaukee. This shifts as parents “restart their child’s therapies as the child heads back to school.”

Agreeing with Olson, Jim Cox, director of pharmacy at Coborn’s Inc., a 38-store regional grocery/pharmacy chain in Minnesota, says ADHD is the primary area in which those pharmacies see an increase in prescriptions as students return to school. ADHD becomes more evident as summer sports and activities wind down, he says. “In many cases, we’ll dispense more than one bottle, one for the child to have with him in school and one to keep at home,” he said.

Tracy Bayer, PharmD, a pharmacist at Hillcrest Pharmacy in Vernon, TX, says...
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she sometimes needs to order extra supplies of drug products for ADHD as the demand increases in September.

**Medication Considerations**

Common prescription drugs for the treatment of ADHD, according to Christopher Nadeau, PharmD, a fourth-generation pharmacist at Bedard Pharmacy in Lewiston, ME, are a combination of stimulant drugs, which are also Schedule II drugs, and nonstimulant drugs (See Box). These drugs can be supplemented with over-the-counter items.

In addition to prescription drugs, Olson says Skywalk recommends nutritional supplements and vitamins for ADHD. Since ADHD therapies can have the side effect of a reduced appetite, the pharmacists may recommend an appetite stimulant, he says. Additionally, melatonin may be recommended to help with sleep problems, another side effect.

In Maine, Nadeau has a different approach. “I generally don’t recommend OTC products as much as I do lifestyle changes,” says Nadeau. “I usually suggest that the patient gets ample time for physical activity and develops good sleep habits. This has helped a few of my patients lower their dose, or get off the medication altogether.”

Bayer says Hillcrest Pharmacy doesn’t dispense many OTC products for ADHD. It is generally more cost-effective for parents to request a prescription drug, which can be covered by insurance, she says.

Nadeau says that, from what he has seen in his pharmacy, providers may be seeking alternative treatments before writing a prescription for an ADHD drug; he has seen an overall decrease in the number of prescriptions written. “Many ADHD medications are Schedule II narcotics, which have been scrutinized extensively over the last few years,” he says. He also points out that there are now more resources for families, such as counseling.

**Beyond Dispensing**

The pharmacist can serve as a catalyst in ensuring that a child is properly diagnosed with ADHD. Cox says parents may reach out to pharmacists based on symptoms they’ve seen in their child. Pharmacists can then encourage parents to take their children to a physician for diagnosis. Olson notes that a child’s teacher may often be involved in helping to secure a diagnosis as well.

Nadeau says that he refers students and families to resources in the community, when applicable.

Kathleen Gannon Longo is a contributing editor.

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**BACK TO SCHOOL PREP TIPS**

Pharmacists should prepare for other health issues that become more common as children go back to school. “We generally see an overall increase in traffic through the store,” at this time of year, says Olson. “We make sure we are stocked up on head lice treatments and combs. We are prepared for viral infections with a supply of fever reducers and for infections with antibacterial drugs. And it’s important for parents to make sure that their child’s asthma medications haven’t expired, since asthma may be induced by the exercise involved in school sports.”

Walgreens also takes steps to meet the needs of students returning to school. “Each year, our pharmacy and store team members take measures to help ensure that our customers get all the items they need in preparation for back to school,” says a Walgreens spokesperson. The stores stock up on school supplies, lice treatments, first aid products, inhalers, among other items.

At Hillcrest in Texas, pharmacists prepare for injuries from sports as September approaches. The store doesn’t carry sport braces, but can order them for the next day’s delivery, says Bayer. Pharmacists at that location also see a higher demand for vitamins as students return to school.

Vaccinations are an area of focus at Coborn’s, where pharmacists “want to make sure that students are up to date on the required vaccinations before they go back to school,” says Cox. “We always notice an uptake in some of these vaccines, based upon the requirements of a specific school district,” Cox says.

Walgreens also encourages parents and children to visit their local Walgreens for back-to-school immunizations, since an appointment is not required. Walgreens Healthcare Clinics also offer sports and school physicals.

Olson notes that back to school is an appropriate time to establish a relationship with the younger set. “The pharmacist can help educate the child on the proper way to use medications, such as inhalers for asthma and EpiPens.”

The pharmacist can help educate the child on the proper way to use medications, such as inhalers for asthma and EpiPens.”
Formulary Drug Exclusions on the Rise

Here’s what’s driving the trend and how decisions are made.

A 51-year-old female patient has been taking Forteo (teriparatide) for osteoporosis for the past year. Her insurance company notifies her that the drug is no longer on its formulary. Her health plan, following the national preferred formulary (NPF) developed by Express Scripts, switches her to Tymlos (abaloparatide), a new drug for osteoporosis and new to the NPF for 2018. The reason is that Tymlos has a lower overall wholesale acquisition cost (WAC) than Forteo with clinical equivalency and similar outcomes.

Similar scenarios have played out across the country as health insurers and PBMs exclude certain drugs on their formularies to decrease drug costs.

Express Scripts excluded 64 drugs in 2018, bringing its total since 2014 to 159 out of more than 3,791 available drugs. According to the St. Louis-based PBM, as many as 99.22% of patients will not receive any changes to their drug coverage. If a patient needs a drug not on formulary, the PBM says it will provide exceptions to cover the medication.

From 2014 to 2018, Express Scripts’ exclusions are expected to save participating NPF clients and patients $7.4 billion, with $2.5 billion this year.

CVS Caremark anticipates savings of $13.4 billion from 2012 to 2018 for its PBM clients due to lower cost brands and increased use of generics, according to the PBM’s August 1, 2017, issue of Insights commentary. The publication also reports that during 2018, the PBM removed 17 products in 10 drug classes from its standard control formulary while adding back others. CVS estimates that 99.76% of its members will stay on their current therapy.

Ken Majkowski, PharmD, chief pharmacy officer at Bethlehem, PA-based FamilyWize, a community-based organization that offers a free prescriptions savings program, says PBMs seem to be excluding more drugs than in the past. He says that’s because most drugs being approved are expensive specialty drugs, and because there might be viable less-expensive therapeutic alternatives available.

The Exclusion Process

Adam Kautzner, PharmD, vice president of supply chain strategy for Express Scripts, says medication decisions are based primarily on clinical appropriateness and effectiveness, followed by comparing WAC to net cost. “If net cost is not where it should be, we will exclude a drug and try to negotiate on behalf of employers,” he says.

Express Scripts’ Pharmacy and Therapeutics (P&T) Committee analyzes new drugs, FDA-approved indications for existing drugs, clinical line extensions, and published trends that might affect previous formulary placement decisions.
Because there is no transparency in PBM contracts, there is no evidence or way to know if outcomes, cost, and comparative value are being considered.”

CHERYL LARSON, MIDWEST BUSINESS GROUP ON HEALTH

"Because of our clinical-first approach, we need to ensure there are clinically appropriate options for patients in each therapy class," Kautzner says. "Simply put, if there isn't competition within a specific class, we cannot exclude a drug—except if our P&T committee determines it's unsafe and clinical benefits don't outweigh the risks. Alternatively, the more options within a therapy class, the more opportunities we have to drive down the cost of the medications while still preserving choice for members."

David Lassen, PharmD, chief clinical officer of Prime Therapeutics, explains that in making formulary recommendations to its clients—including which drugs to exclude—the PBM helps ensure members will have access to the right mix of drugs needed for the best health outcomes, while driving toward generic and preferred brands that are equally as effective and safe for members.

"The formulary development process is always changing based on both new-to-market brands and generics. We look at safety, efficacy, and availability of other treatments for a given condition," Lassen says. "As more high-cost drugs come to market, the number of exclusions may go up if other equivalent therapies are available."

Each quarter, Prime reviews NetResults, one of its standard formularies first introduced in early 2017, so that it reflects current market offerings.

Like Kautzner, Lassen says Prime believes that the clinical merits of a drug should be at the forefront of formulary decision making and that, once clinically supported products are determined, cost can be a final deciding factor.

In its first year, NetResults delivered a decrease in net drug trend of 11% compared to its non-NetResults population. To date, Prime has seen an $8 to $14 per-member-per-month average savings range through the first year post implementation of the formulary. In a cohort analysis of continuously enrolled members in NetResults and nonmembers, there was an 8% point decrease for members.

Criticisms and Concerns
Cheryl Larson, president/CEO of the Midwest Business Group on Health, a pharmacy data and analytics company, says exclusions are mostly brands that have multiple products in the same therapeutic class and high utilization, and are more expensive than other clinically equivalent drugs in the same class.

Majkokwski says that as generic equivalents within a therapeutic class become available, PBMs have greater ability to steer members to lowest price alternatives. Express Scripts also supports excluding drugs that are accompanied by a manufacturer copayment discount card. "These cards do not lower costs for plans and often lead to higher costs because the plan is then paying its share on a more-costly medication," he says.

Prime’s exclusions typically involve brands with OTC alternatives, high-cost brands (not necessarily those with only rebated alternatives), and high-cost generics that aren't on a maximum allowable cost list and exceed specific clinical and cost criteria, Lassen says.

MORE INSIGHT COMING SOON
Express Scripts does not exclude drugs for inflammatory conditions, multiple sclerosis, and diabetes, factors that could change for 2019.

Which Drugs Are Excluded
Thomas Borzilleri, CEO of Intelisys Health, a pharmacy data and analytics company, says exclusions are mostly brands that have multiple products in the same therapeutic class and high utilization, and are more expensive than other clinically equivalent drugs in the same class.

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Mari Edlin is a contributing editor.
New Drug Pricing Tools Could Save Money

Tools can help providers and pharmacists make higher-value medication decisions.

Drugs are often considered a commodity, but unlike other products, most people don’t know what they really cost. “We live in an era where you know the exact price of a car before you buy it and of a cab ride before you take it, but healthcare remains one of the few areas where there is still a need to lift the veil on drug pricing to patients,” says Richard Cohan, president, Patient Innovations Division, with DrFirst, a Rockville, MD-based provider of medication management solutions.

In response to the lack of transparency, health organizations are creating tools that deliver patient-specific drug price information, helping physicians and pharmacists make more cost-effective decisions at the time of prescribing. Such tools could also help reduce the number of abandoned prescriptions, those left at pharmacies by patients who balk at the prices.

Solutions for physicians

In April, San Francisco-based Blue Shield of California and Gemini Health, a health IT firm in Sausalito, CA, collaborated to launch the Drug–Cost Transparency Service. Matt Nye, PharmD, vice president of pharmacy services for Blue Shield, calls it a real-time benefits tool.

Operating through a provider’s EHR, the service displays drug price information, including:
- Patient out-of-pocket costs for selected medications based on a patient’s health plan benefits and formulary.
- Accurate total drug cost savings (based on actual payer costs and rebates) for up to three lower-cost, dose-matched, clinically equivalent alternative medications.
- Total drug costs to the plan.
- Accurate patient cost and total savings for alternative pharmacies (e.g., specialty or mail order).
- Whether prior authorization is required, and/or alternative medications that don’t require it.
- Any coverage notices that would create pharmacy callbacks to the prescriber’s office.

“If we can provide patient-specific, accurate information at the point of prescribing—at the point of decision making—doctors will prescribe what is covered and is most effective,” Nye says. “An EHR needs to include decision support.” He says the tool could lower out-of-pocket costs, reduce the need for medical office staff to check on prior authorization, and improve adherence.

As a physician, Edward J. Fotsch, MD, founder and CEO of Gemini Health, agrees that doctors don’t know the cost of drugs for patients when they prescribe them, though they would like to help patients lower their drug costs.

“Doctors also would like to receive fewer callbacks from a pharmacy when they prescribe a drug requiring prior authorization or one that is too expensive,” he says.

Though data regarding how the tool is impacting overall costs is not available yet, Fotsch expects it will lead to savings for patients, payers, and providers, and provide better drug access for patients and cleaner prescriptions for pharmacists, without prior authorizations or denials.

The tool is available to Blue Shield of California’s network of physician groups at no cost, but members of other health plans using the same physician network can access the service through Gemini. The IT company is working with individual medical groups to integrate the service into their EHRs and provide training and support.

Although no physicians are using the service at press time, because they are still working on EHR integration, Nye estimates that 30% to 40% will have
Cohan agrees that widespread adoption of a drug cost transaction is dependent on the willingness and ability of EHR vendors to support integrations with health plans and to give their customers access, particularly in the client server environment.

**Solutions for pharmacists**

To keep drug costs in tow—especially for patients with high-deductible plans—CVS Health developed two new tools—the Pharmacy Rx Savings Finder and a real-time benefits program.

Launched in April, the real-time benefits program—similar to Blue Shield’s product—provides real-time member-specific drug costs and up to five lower-cost alternatives based on a patient’s formulary to prescribers through their EHRs. If prior authorization or step therapy is required, prescribers can immediately submit an electronic prior authorization request and in most cases, receive a near-real-time decision.

Members can access information through the member portal.

The other tool, the Pharmacy Rx Savings Finder, lets the company’s retail pharmacists evaluate individual prescription savings opportunities at the point of sale. Designed initially for CVS Caremark PBM members, the tool indicates:

- If a prescribed medication is on a patient’s formulary and if it is the lowest-cost option available.
- If there are lower-cost options covered under a patient’s pharmacy benefit, such as a generic medication or therapeutic alternative with equivalent efficacy of treatment.
- If a patient might be able to save money by filling a 90-day prescription rather than a 30-day one.
- Other potential savings options for eligible or uninsured patients if no generic or a lower-cost alternative is available.

“These tools help improve the patient experience and lower costs,” says Casey Leonetti, PhD, senior vice president of PBM innovation, CVS Health. “Specifically, they help avoid rejects at the pharmacy that can lead to primary nonadherence of required therapies; they save patients out-of-pocket costs by helping them maximize their drug benefit to find the lowest cost option; and they reduce administrative burden and costs for providers and plans.”

Early results show that prescribers accessing the information switched a patient’s drug from a noncovered drug to a drug on formulary 85% of the time. When a patient’s drug was covered, prescribers switched the patient to a lower cost alternative 30% to 40% of the time, saving an average of $75 to $100 per prescription, according to CVS Health.

Mari Edlin is a contributing editor.
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The evolving and complex nature of healthcare for HIV patients has made an interdisciplinary team approach the norm for treating the estimated 1.1 million people living with the disease in the United States. The pharmacist’s role on the team includes dispensing medications, educating and providing psychosocial support to patients, treatment monitoring, and advising the rest of the team on new pharmacological developments.

It’s a role Amina Abubakar, PharmD, AAHIVP, knows well. Her first exposure to how devastating HIV came as a child growing up in Kenya in the 1990s. She witnessed people dying every day from the disease, and watched grim HIV warnings on TV. “I think I had an emotional scar and wanted to be a solution to this epidemic,” she recalls.

Abubakar graduated from the Philadelphia College of Pharmacy, where she completed an HIV rotation. She also became credentialed by the American Academy of HIV Medicine (AAHIVM) as a certified HIV Pharmacist.

Today she owns and operates Rx Clinic Pharmacy in Charlotte, NC, serving more than 500 HIV patients there and at the nearby Ballantyne Family Medicine East clinics.

**Going Beyond the Pills**
Abubakar understands the social and medical aspects of the disease and its changing demographics. “Our role in HIV medicine is beyond the pill,” she explains, adding that pharmacists involved in HIV care are part of an important population health management strategy. “Learning how to treat an HIV patient as a whole has become crucial for us because now we’re having patients with HIV who are in their 70s and 80s. We need to be a one-stop shop that knows how their HIV will be affected by everything else in their life.”

The challenges of caring for HIV patients are many. For example, Abubakar notes that opioid abuse is an ongoing concern. Her pharmacists are trained to understand the drug interactions between HIV medications and illicit drugs.

“We tell patients, you can be honest with us. Tell us what you’re using so we can make sure you’re on the right drugs for HIV,” she says. It’s a trust-building approach that Abubakar says has paid off with improved adherence, which leads to better outcomes on more than one level.

The goal is to get patients to take their HIV medication consistently to reduce their viral load. Then the pharmacist can discuss with them strategies and resources to get them off the other drugs they’re abusing, such as cocaine and alcohol, she says.

**Collaborating with Physicians**
At Ballantyne Family Medicine, Abubakar collaborates closely with Wesley Thompson, MHS, PA-C, AAHIVS, a Duke University graduate who has been in practice since 1987 and is one of the first physician assistants in the nation to be certified as an HIV specialist. He advocates strongly for community pharmacists to be included on the treatment team.

“They are absolutely positioned to be exactly what we need. They work from...”
protocol, they extend the prescribing provider’s ability, and the overall cost of the system is less,” he notes. “They are more than a resource. They’re an asset and a colleague to me, and they extend our ability to be more comprehensive in care.”

Abubakar and the other pharmacists who work with Thompson interact with HIV patients on multiple levels, including conferring on abnormal lab results, side effects, and other acute issues. As a result, they help to build up the patients’ level of security and confidence, improving their adherence and overall continued care, Thompson says. “Many patients get in front of me and it’s as if I’m an authority figure—they get the ‘deer in the headlights’ look,” he explains. “But the pharmacist is infinitely more approachable. They get to hear the nuts and bolts that I don’t get to. I would not want a clinic without them,” he says.

Changing World of HIV
Roger Paganelli, RPh, has been involved in HIV care since graduating from St. John’s University College of Pharmacy in 1987, during the early years of the epidemic. Over the subsequent decades, the co-owner and supervising pharmacist at Mount Carmel Pharmacy in the Bronx, NY, has been through a major evolution in treatments.

“People were dying at a severe rate because they couldn’t get a handle on how to manage the disease from a pharmacological perspective. To say that it was profound is an understatement,” he remembers.

“Now there are mainstream commercials for Truvada and the PrEP program. I think the world has changed dramatically,” he says.

Not everything has changed, however. The HIV patients he sees still experience bouts of depression, mental anguish, and general anxiety disorder that require talk therapy and psychiatric medications. Patients with comorbidities—including diabetes and hypertension—are an ongoing concern. “We have to help them understand that they have to be on multiple medications to stay alive,” Paganelli notes.

To address the issue of adherence, Mount Carmel Pharmacy relies on a medication synchronization program. “Once we get them on a schedule, we can make sure that the patient gets their medication every month,” Paganelli says. “We make sure that the patient is contacted, that we have a med reconciliation with them, and that they’re staying compliant.”

We tell patients, you can be honest with us. Tell us what you’re using so we can make sure you’re on the right drugs for HIV.”

FOUR WAYS TO HELP HIV PATIENTS
1. Take the time to get to know HIV patients in-depth as individuals. “Spend more than just a couple of minutes at the counter. Take them private and make them understand that the disease is manageable and is not a death sentence,” says Paganelli.

2. Encourage patients to keep their appointments with their doctors and to make sure their blood results are done on a regular basis. “And encourage them to keep themselves as healthy as possible because that will ultimately, along with the right drug therapy, give them as long a life as they can possibly have,” says Paganelli.

3. Brush up on your skills and knowledge. Abubakar urges pharmacists to become more involved in HIV treatment and prevention while acknowledging that many aren’t as comfortable in the HIV arena as they are treating patients with other chronic diseases. “HIV is a life-long condition, so you will be managing these patients for a long time with newer medications onboard,” she says. Thompson says he has a very easy question for pharmacists who don’t feel at ease treating HIV patients. “Are you comfortable handling diabetes?” he asks. “If so, let me remind you that statistically people live longer and healthier with HIV than diabetes. If you can handle diabetes, it won’t take much for you to feel comfortable with HIV.”

4. Work closely with other providers. For pharmacists who encounter resistance to their role on the interdisciplinary care team, Thompson offers these words of advice: “Don’t be discouraged when clinicians don’t understand your role. Forgive them because bitterness will only result. Work with them and educate them. As a community pharmacist, it will be worth it to endure.”
Heart disease is the leading cause of death in the United States and accounts for more than $200 billion each year in healthcare costs, according to the CDC. Increasingly, pharmacists are practicing in cardiology across the spectrum of care ranging from ambulatory clinics that specialize in heart failure to intensive care units where patients have recently been diagnosed with decompensated heart failure or are recovering from cardiac surgery.

A multidisciplinary team with a pharmacist benefits patients with cardiovascular disease since they often have comorbid conditions and complex medication regimens that can include the use of high-risk medications. A pharmacist with expert knowledge in cardiology can ensure optimization of medical therapies, drug interaction screening, and provide drug information.

Specifically in the ambulatory care setting, pharmacists specializing in cardiology can perform frequent visits to ensure heart failure patients get their target doses of medications that reduce morbidity and mortality, or adjust anti-hypertensive medications to reach the recommended blood pressure goal. Optimizing the medication regimen, coupled with concentrated education on both the disease state and drug therapies, can help keep patients out of the hospital, decrease complications, and improve overall quality of life.

In the acute care setting, many cardiovascular patients receive multiple diagnoses. During an initial hospitalization, a patient may present with symptoms of a heart attack, and then be diagnosed with diabetes, hypertension, and hyperlipidemia. Pharmacists make a huge impact on these patients by offering guidance on selecting a medication regimen that treats multiple disease states. During transitions of care, pharmacists also help select a regimen that allows patients to manage their own care at home.

Many of these patients need multiple medications to adequately treat their cardiovascular diseases. Cardiology pharmacists are uniquely positioned to provide in-depth education to patients who are on high-risk cardiology medications such as anticoagulants and antiarrhythmics. Cardiology pharmacists can also aid in quality improvement projects. Evaluating the appropriate prescribing of high-risk therapies or attainment of the therapeutic range for anticoagulants can help in medical decision-making. Pharmacist guidance can ultimately lead to enhanced utilization of medical therapies and improved patient outcomes.

Lastly, participation in order set development is a key role that pharmacists can play in improving care in cardiology. The creation of order sets for disease states like acute coronary syndromes can lead to increased prescribing of newer antiplatelet therapies or aid in smoking cessation.

Consider Board-Certification in Cardiology

An opportunity to ensure optimal care in various practice settings

CARDIOLOGY CERTIFICATION

The Board of Pharmaceutical Specialties (BPS) announced creation of a specialty in cardiology in February 2017. This specialty is designed to acknowledge the skills and abilities of a pharmacist who provides individualized care to patients with or at risk for cardiovascular disease. BPS will begin to administer the exam to become a Board Certified Cardiology Pharmacist (BCCP) this fall. Pharmacists with an active license will be eligible if they meet one of the following requirements:

- Four years of practice experience with at least 50% of time spent in cardiology pharmacy activities
- Completion of a PGY-1 residency plus two additional years of practice experience with at least 50% of time spent in cardiology pharmacy activities
- Completion of a specialty (PGY-2) residency in cardiology pharmacy.

BPS certification will increase recognition by other healthcare professionals of pharmacists as expert practitioners in cardiology.

John Lindsley, PharmD, BCPS-AQ
Cardiology, is a clinical pharmacy specialist in the Cardiac Care Unit at The Johns Hopkins Hospital in Baltimore.
Adapting and Innovating in Pharmacy: Keys to Success

URAC report outlines the current challenges and future paths in community pharmacy.

NEW WAYS TO COMPETE

1. **Specialty pharmacy**: To keep themselves competitive, many pharmacies are looking at entering this arena, Bonome notes. Specialty pharmacy is enlarging rapidly as more drugs are approved for complex conditions like cancer, hepatitis C, HIV, and autoimmune diseases. These drugs often require more patient education and counseling, more interactions with other health providers and health plans, and usually carry large price tags. “If you’re going to head down that path, really do your research and make sure you know what you’re getting yourself into, because it really is a different practice model,” she says.

2. **New technologies**: New technologies can also help pharmacies distinguish themselves from other pharmacies in their communities. “The challenge is identifying the new technology that will actually improve operations,” the report adds. Software and hardware ranging from phone apps to smart pill vials can help pharmacists improve their patients’ medication use and adherence.

3. **Provider status**: Attaining provider status as a pharmacist, something not possible in every state, can also be a way for community pharmacists to position themselves as full members of the healthcare team, the report says. Provider status can help pharmacists be reimbursed for pharmacy care and clinical services. Another way to do this is through collaborative practice agreements with physicians or physician groups that specify what patient care services can be provided by the pharmacist. Although the NCPA is in favor of obtaining provider status for community pharmacists across the country, it is not the only way for pharmacists to be reimbursed for clinical services, says Proctor. “There’s certainly lots of opportunities for pharmacists to be paid for services,” he points out. There are initiatives like the Community Pharmacy Enhanced Services Networks, which link pharmacies with medical practices.

The growth of the specialty pharmacy market, making the right choices in technology, attaining provider status, securing collaborative practice agreements, and retail pharmacy consolidations: These are five of the challenges facing community pharmacies in a healthcare economy that is becoming based on value, says a new report.

The report was released by URAC, the accreditation organization that focuses on programs that manage healthcare.

“Pharmacies that dispense traditional medications (as opposed to specialty medications) are struggling with maintaining profits, which escalates the pressures of competition even further,” says Heather Bonome, PharmD, URAC director of pharmacy.

The report is an opportunity to share information on where the healthcare industry and the pharmacy space are heading, Bonome says. Many pharmacies are looking to new sources of revenue, such as increasing vaccination services to include travel immunizations, which only about 23% of pharmacies that vaccinate provide, the report notes. Other new revenue sources include offering health screenings, smoking cessation support, and direct lab testing.

The report notes the spate of consolidations by pharmacy chains as being a challenge for community pharmacy. Kurt Proctor, PhD, senior vice president, NCPA, notes that the number of independent pharmacies has stayed fairly stable.

Third-party accreditation, where an outside agency examines the processes and standards of a pharmacy, can help community pharmacies show that they have the processes and the operational structure in place that can help in obtaining collaborative practice agreements, Bonome says. Accreditation can demonstrate that a pharmacy has achieved established industry benchmarks, she adds. URAC has accredited 300 pharmacies and 439 specialty pharmacies around the country.

Valerie DeBenedette is managing editor of Drug Topics.
A study by the Committee on Homeland Security and Governmental Affairs concluded that 12 of these drugs (60%) had their prices increased by more than 50% in the five-year period while 35% or six of the 20, had price increases of more than 100%.

### Price Increases of Common Prescribed Drugs

Prices for the most prescribed brand-name drugs for seniors increased **12%** every year for the last five years, almost 10 times higher than the average annual rate of inflation.

Anthony Vecchione is executive editor of Drug Topics.

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Supply Chain Excellence

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The abuse of prescription opioids is a multifaceted and complex issue. But the pharmacy is critical in helping address this epidemic. That’s why pharmacy owner David Belew, RPh, hired a patient community care coordinator, Jessica Beasley, who talks with every pain patient who fills an opioid script.

“As an owner of four pharmacies in and around Knoxville, TN, I have a part in this,” Belew explains. “As a provider for chronic pain patients, I have a responsibility to act. Everyone in the pharmaceutical supply chain has a responsibility to act. And it has to be more than a bunch of people sitting around a boardroom table talking the issue to death.”

Pharmacists are not the ultimate decision makers in opioid prescribing, but they are the most accessible and most trusted healthcare professionals. That makes them key players in opioid use.

“Intervening in pain is just as important as intervening in heart failure or asthma or anything else,” says Bob Mauch, executive vice president and group president, Pharmaceutical Distribution and Strategic Global Sourcing at AmerisourceBergen. “Pharmacists have a responsibility to intervene.”

AmerisourceBergen provides drug deactivation products and pouches to municipalities and nonprofits through a grant program by the AmerisourceBergen Foundation. The resources enable patients to dispose of unused or expired prescription medications in a safe and effective manner.

Today’s opioid epidemic demands action, attention and a collaborative approach,” Mauch says. “We have to be part of the solution. It is our responsibility to help.

“We did a survey and approximately 60% of opioid patients had never had a conversation with their pharmacist or anyone else about safe use, storage, or disposal of prescription opioids,” says John Parker, senior vice president of communications for the Healthcare Distributors Alliance (HDA). “Nearly 70% had never had a conversation with a healthcare provider about alternatives to opioids. And 90% kept unused opioids for future use.”

HDA’s launched Allied Against Opioid Abuse (AAOA) earlier this year. The national awareness and education campaign brings together HDA, NCPA, National Alliance of State Pharmacy Associations, National Council on Patient Information and Education, and other organizations. AAOA has a number of consumer-focused education materials and is working with its pharmacy partners to roll out a tool kit to independent pharmacies in Connecticut, Florida, Minnesota, Ohio, Pennsylvania, and Tennessee in August. Other states will follow later in the year, Parker says. The pharmacy toolkit will also be available online at www.AgainstOpioidAbuse.org/PharmacyToolkit.

The goal is to help pharmacists engage and educate patients about the safe use, storage, and disposal of prescription opioids. “Every patient has the right to receive full information to make an informed decision about prescription medications,” Parker says. One suggestion is requesting partial fills to limit the supply at home and reduce the risk of misuse.

Patients should fully understand the risks of opioids, including physical dependence and addiction, and talk to a pharmacist about those risks. And every patient has the responsibility to help prevent misuse and abuse by safely storing opioids at home and safely disposing unused medications.

Belew, a Good Neighbor Pharmacy member, isn’t waiting for the toolkit. He hired Beasley, a professional educator who is in recovery herself, to counsel patients about the potential risks and benefits of opioids. She meets with every opioid patient at least quarterly, and as often as the patient wants.

Belew’s pharmacy staff reviews each patient’s profile and medication history at least monthly as part of the medication synchronization program. As Beasley or pharmacists see changes in individual medication attitudes or use, the pharmacy encourages prescribers to take another look at the patient’s pain needs and drug regimen.

Fred Gephart is a contributing editor.
I talk to doctors every day. Some I would even call my friends. Most are incredibly appreciative of the services we pharmacists provide.

But communication is not always easy. We both are busy and we don’t share an administrative assistant who can schedule regular meetings to catch up. I really can’t speak for every pharmacist, but if I could get just 10 minutes of time on a conference call with local physicians here are seven things I’d tell them.

1 **Call Me Sometimes.**
   Some of you call me all the time, about patient refill patterns, drug interactions, and drug coverage information. But some of you never call at all. Heck, I’ll give you my cell phone if you want a direct line. We’re partners in this community and I want you to pick up that phone from time to time if you have a question or a concern. You can text or email me if you prefer. But I want you all to know that’s what I’m here for.

2 **Check in with Your Office Staff.**
   In my experience most doctors are brilliant clinicians, but are sometimes a bit weak on office management, especially on how refill requests are done. So you hire amazing office managers who typically run a tight ship. But you should check the ship from time to time if you have a question or a concern. You can text or email me if you prefer. But I want you all to know that’s what I’m here for.

3 **Print Clearly.**
   This is becoming less problematic with printed and electronic prescriptions, but it still applies to some of you. Print clearly! I know you are busy. So is my staff and your staff. It slows us all down if my team has to call your team to clarify a messy order. And it isn’t just hand-written orders. Some electronic prescriptions have directions or dosages that make no sense. I recommend scheduling time to just read and review orders that leave your practice electronically. Do they demonstrate the quality you expect?

4 **Prevent a Call-Back with a Clarifying Note.**
   Are you going to write an unusually high dose or mix two medications that can sometimes interact? Drug therapy isn’t always black and white. Sometimes the benefits outweigh the risks. Maybe you thought about this. But maybe you didn’t. Save us and your staff a lot of time by indicating your understanding of this on the prescription.
   Also, speaking of clarifying, it wouldn’t hurt to add a diagnosis code to help us understand the dosing you wrote for.

5 **Optimize Prescription Software for Safety and Clarity.**
   If you are printing prescriptions from your office computer, you can probably improve some of the features to minimize an error. For example, don’t prescribe by the generic name only. This is especially true for combination HIV therapy or other combination drugs. Writing for hydroxyzine? Which one?

6 **Be More Careful with Opioids than Ever Before.**
   Let’s talk about opioids. We’ve got a problem on our hands as a nation. We can’t turn back time and remove narcotics from the market. Nor should we.
   But we don’t need to prescribe so much! Most of you have caught on, and have greatly reduced your volume. Others appear to be indifferent, defiant, or clueless. Stop it! I implore you to make your patients sign a contract that includes no doctor-shopping, ER-shopping, pharmacy-shopping, or early refills. Use the prescription drug monitoring program. Also, insist on and conduct drug-screenings and random pill counts. I’ll even do the pill count for you.

7 **Thank You**
   I want you to know I appreciate the care you give to our patients. I know you sometimes work late hours. I know you have a ridiculous amount of paperwork to do. Don’t let it go to your head, but you do great work. Not only as a pharmacist, but as a patient myself, and father of four children, I definitely am grateful for the physicians in my life.

Jason Poquette, RPh, lives in Whitinsville, MA.

Starting a patient on bupropion? There are various formulations for the same strength. Never write for insulins by generic name only. You can help us prevent errors this way. Also, make sure your prescriptions have the patient name and date of birth printed clearly as well.

**THE LIST**

Jason Poquette, RPh

**7 Things Every Pharmacist Wants to Tell a Physician**

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Jason Poquette, RPh, lives in Whitinsville, MA.
“Virtual Staff” for Community Pharmacies

Technology can help expand business and improve patient outcomes

Matt Robinson, RPh, pharmacist-in-charge at Poole’s Pharmacy Care in Owensboro, KY, was looking for a way to improve patient adherence scores.

He found a solution in the Central Sync program, a component of VRxAssist from PrescribeWellness that helped him to identify the right patients for the virtual program which maximizes adherence scores. Poole’s was a beta test site for VRxAssist.

“They enrolled the first 25 patients for us and coached us along the way. We were on-boarded into Central Sync on November 27, 2017 with one patient previously enrolled and Star Ratings of 3.36. We were off-boarded on January 24, 2018 with 66 patients. To date, we have 95 patients enrolled and Star Ratings of 4.52,” says Robinson.

CMS developed the Star Ratings system to help consumers compare Medicare Advantage and Medicare Advantage Prescription Drug Plans based on factors of quality, cost, and coverage.

Pharmacies are rated on how adherent patients are, especially those taking medication for diabetes or hyperlipidemia, or those on ACE inhibitors, Robinson points out. “Using reports on StarWellness and software on Equipp, we enrolled outliers in med sync and got them compliant.” This helped to drive up his pharmacy’s Star Ratings.

Med Sync or medication synchronization, addresses the adherence problem by enabling pharmacies to fill patient prescriptions and sync all of them for a single, convenient pick-up day each month.

It allows pharmacies to optimize and streamline work flow while creating an opportunity for pharmacists to provide monthly check-ins and medication therapy management, focused on topics such as proper medication usage or mitigating side effects.

Robinson says that major pharmacy chains and thousands of independent pharmacies have implemented Med Sync, due to its ability to drive patient wellness, its compatibility with Medi-longer calling as much and the lack of phone calls opens up times for other things, like vaccinations, inventory management, marketing their compounding services.

“When they become adherent, we are sparing them from side effects down the road, particularly when it comes to diabetic patients and good kidney function. In Kentucky, there are high rates of obesity and diabetes is a huge part of that. Compliance is vital for these populations. It does benefit us, too, of course, but helping the patients become more compliant is the first priority.”

Al Babbington, CEO of PrescribeWellness says that community pharmacies can’t just rely on dispensing revenue. They need to take advantage of new and emerging payment models. But that leads to a quandary. They need additional staff to get the most out of new and emerging payment models, but they can’t justify the cost.

The company launched VRxAssist, in July and describes it as a turnkey “virtual staff” solution designed to provide pharmacies with support to expand services and capitalize on new revenue opportunities.

Pharmacies license the software suite on a term basis, with a separate agreement to license the virtual staff for as long as they need.

Anthony Vecchione is executive editor of Drug Topics.
Ten Wearables to Watch

Tech collaborations are making healthcare wearables more useful and robust.

The healthcare wearables market experienced a boost in 2017, with more than 10% market growth between 2017 and 2018. These are the devices that can strap onto your wrist or be worn as a patch (or a bra!) and that can collect and deliver information about your health status.

As more of the apps that connect with them come to market, users are looking for more sophisticated devices, says Ramon T. Llamas, research director for wearables at the International Data Corporation (IDC), a market intelligence firm.

Vendors, including start-ups, have created devices with features and services that make wearables more advanced, says Llamas. “Going forward, the next generation of wearables will make the ones we saw as recently as 2016 look quaint.”

Smartwatches continue to be the most popular kind of wearable device, taking up about 33% of the market this year, according to IDC. In total, IDC estimates that 132.9 million wearables will be shipped this year.

Many tech companies are thriving by integrating their devices with technology or software from other organizations that already have a footprint in the healthcare industry. For example, Fitbit announced a collaboration with Google in April 2018, giving Fitbit the ability to connect its fitness data with electronic health records secured by Google.

In March 2018, Apple announced a partnership with 40 health systems that will allow patients to access their medical records via their iPhones, integrating Apple Health data from fitness and wellness apps.

Wearables are having an immediate impact on patient care because of their quick adoption, says Ilan Reingold, vice president of business development and marketing at Altair Semiconductor. Altair has collaborated with Ericsson and Sony Mobile to create a continuous glucose monitor (CGM) that utilizes cloud technology and is not dependent on mobile connectivity.

Reingold says that low-power affordable technology that easily integrates with existing health technology will allow wearables to be more accessible and meaningful to users. “The core connectivity technologies powering health wearables are integral for providing low-power, highly integrated solutions that enable users to benefit from longer battery life,” Reingold says. “Health monitors will continue to become easier to use and remain connected anytime, anywhere.”

Here are 10 healthcare wearables to watch

1. Oska Pulse

Oska Pulse, a palm-sized patch, is used to alleviate chronic pain and reduce the need for opioid use. The device can work on multiple parts of the body, such as knees, back, and other muscles and joints, for chronic pain relief. It uses pulsed electromagnetic fields (PEMF) to dilate blood vessels and help reduce inflammation and pain. Aside from slight warming due to increased blood flow, Oska developers say users don’t feel much from the patch during 30-minute therapy sessions.

A mobile app, called Oska Pulse Active, works remotely with the wearable and features a pain tracker that allows users to track pain management on the app and through a web portal. Oska Pulse is FDA registered as a wearable device that delivers PEMF at a safe rate for home use and is already on the market.

2. E-vone smartshoe

The E-vone smartshoe is for seniors and others susceptible to falls. It notifies family and caregivers in case of abnormal movements or inaction. The shoe is equipped with a GPS monitor, motion sensors, and a vibration point. If the shoe perceives an abnormal movement such as a fall, caregivers (predetermined in advance by users) are alerted.

So far, the shoe can be monitored in more than 120 countries. The French company says the shoe will be available to purchase in the United States in the first quarter of 2019.

CONTINUED ON PAGE 32>
3. **UV Sense**
Cosmetic company L’Oreal has partnered with the La Roche-Posay skin care brand to develop wearable technology to help users track ultraviolet exposure and decrease overexposure to sun rays that can lead to skin damage. The UV Sense is a blue patch-like device that can fit on a thumbnail and works with a mobile app to track up to three months of data on UVA and UVB exposure.

Data is transferred from the patch to the user’s mobile app and then is compiled in a profile to help users change habits that could lead to sun damage. The UV Sense will be available in small quantities this summer, with wide release in 2019.

A slightly larger version using the same technology, called My UV Patch, is currently on the market.

4. **Ericsson, Sony Mobile, and Altair Continuous Glucose Monitor (CGM) wristband**
The result of a collaboration between technology and healthcare companies, this CGM will alert users to potential problems with blood sugar. The wristband will display glucose levels, activity, sleep information, and heart rate. Using Sony cloud technology and a smartphone app, users will be alerted if glucose levels drop.

Altair’s technology, called LTE-M, allows the device to communicate through the Sony cloud without a mobile phone for connectivity. The LTE technology allows for affordable, low-powered use of end-to-end connectivity that could help expand electronic health and wearables market, according to the wristband’s creators. The device was prototyped at the Mobile World Congress in February 2018, and the plan is for it to hit the market in 2019.

5. **My BP Lab**
After a pivot to focus on healthcare technology, Samsung is engaged in several healthcare wearable product integrations using virtual reality and mobile connectivity. My BP Lab mobile app utilizes the optical sensor embedded in the Samsung Galaxy S9 and S9+ phones. The app allows for real-time monitoring of the demand placed on the user’s heart and is monitored through a University of California, San Diego program.

To take part in the program, users must be 18 years old, fit certain health criteria, and opt in. Blood pressure is measured directly through the device without the use of external hardware. Samsung aims to give users more accurate feedback on how daily habits can affect blood pressure and stress levels. Through the app, the partners also hope to use the data of thousands of real-world participants to better understand blood pressure readings.

At the HIMSS conference in March 2018, Samsung announced plans to make the Samsung Health service more robust. This includes more options on the Gear S3 Smartwatch and the GearVR virtual reality headset, including a program to help people with type 2 diabetes that is currently available. The all-inclusive Samsung Health platform tracks fitness and wellness measures including weight management, caloric intake, and sleep, and integrates with more than 140 health and wellness apps.

6. **Byteflies Sensor Dot**
This device measures accurate and raw data of a user’s vital signs. The device can be used on different areas of the body depending on the use. Current uses include heart information (electrocardiogram and blood flow), respiration, motion, electrodermal activity, and muscle activity (electromyogram). The device can transfer the user’s data to cloud-based applications via a docking station but can also store data on the device. Byteflies provides raw data to healthcare organizations that use the devices for their patients, and provides data analytics and machine learning to derive clinical insights.

CONTINUED ON PAGE 31
Focused on the future of generics.

Ahead of the curve in quality and value.
**7. Motiv FitnessRings**

This waterproof ring measures activity, sleep, and heart rate. In April 2018, Motiv announced the ring is integrated with Amazon Alexa, and users can ask Alexa about their heart rate. Further developments will allow questions about sleep and other high-level metrics.

Motiv, which launched integrating with Apple platforms, announced a move to launch its system in Android in 2018. Consumers will receive a ring-sizing kit to ensure a correct fit before ordering the ring. Motiv plans to roll out its rings in retail locations this year.

**8. Aira**

Using smartglasses and a mobile app, Aira connects users to agents who can help low vision or blind people navigate the world. The glasses are video equipped with artificial intelligence and augmented reality technology that allows users to access a voice-enabled assistant named Chloe, similar to Alexa or Siri, for real-time assistance. Users also have the option to press a button on the side of the device to access a live agent who can view their environment through the lenses and offer assistance or answer questions.

The glasses come with a subscription-based plan, priority WiFi service in public places, and insurance for the hardware. The assistive service aspect of the glasses is only available between peak hours during the day but will be available 24 hours per day starting in summer of 2018.

**9. Kardia Mobile**

Using a mobile app and a fingerpad that’s smaller than a credit card, this device provides medical-grade single-lead EKG result in 30 seconds. Users can use the fingerpad to receive instant analysis for detecting atrial fibrillation and normal sinus rhythm.

The FDA-cleared device gives users four results: normal, possible atrial fibrillation, unreadable due to too much interference during the recording, or unclassified (when the reading doesn’t easily fit into any of the other category; if this occurs, users can send the analysis directly to the Kardia app or share it with a medical professional). The fingerpad and mobile device is currently available and offers a subscription service that stores unlimited EKG recordings and a monthly report. Kardia is also developing a medical-grade EKG band for the Apple Watch.

**10. iTBra**

The iTBra is a wearable device aimed at helping women with dense breast tissue detect cancer earlier. The device consists of two, wearable breast patches that monitor circadian breast temperature changes within the breast tissue.

The devices communicate with Cyrcadia Health’s core lab for analysis using machine learning predictive software developed by the Nanyang Technological University of Singapore. According to the university, abnormal internal body temperature over time can be an early detector of changes in breast tissue, especially for women with dense breasts who have a harder time with detection during self-exams.

Cyrcadia Health states that wearing the patches for two to 12 hours a day can be as effective as a highly-accurate monthly breast exam. According to clinical trials at Stanford University and The Ohio State University, the device demonstrates an 87% correlation to a clinical diagnosis of breast cancer, including people with dense breasts. The device has received premarket clearance from the FDA and is currently working toward full clearance for marketing purposes by 2019.

Donna Marbury is a writer in Columbus, OH.
In May, the FDA approved erenumab-aooe (Aimovig, Amgen Inc.) for prevention of migraine in adults. It is a human immunoglobulin G2 monoclonal antibody that binds and antagonizes the function of the calcitonin gene-related peptide (CGRP) receptor. CGRP receptor antagonists can reduce the vasodilation and inflammation associated with the pathophysiology of migraines, which can result in fewer migraines.1,2

Efficacy
Erenumab-aooe was evaluated for prevention of episodic migraine in two studies (study 1 and study 2), and for chronic migraine in one study (study 3). All trials were randomized, double-blind, and placebo-controlled. Patients with headache due to medication overuse, or a history of transient ischemic attack, stroke, unstable angina, myocardial infarction, coronary artery bypass surgery, or other revascularization within the previous 12 months of screening were excluded from trials. Additionally, patients with a history of headache related to opiate overuse were excluded from study 3 of chronic migraine participants. Episodic migraine is defined as 4 to 14 migraine days per month. Study 1 evaluated erenumab-aooe in 955 participants who received either 70 mg or 140 mg, or placebo over a 6-month period. Study 2 evaluated erenumab-aooe in 577 participants who received either 70 mg or placebo over a 3-month period. Study 3 evaluated the drug in 667 participants with a history of chronic migraine over a 3-month period. Chronic migraine is defined as fifteen or more headache days and eight or more migraine days per month. In each of the studies, participants were allowed to use acute headache and migraine treatment medications, including NSAIDS, triptans, and ergotamine derivatives. Change in monthly migraine days served as a common efficacy endpoint assessed at 4 to 6 months for study 1, and 3 months for studies 2 and 3. In all trials, groups treated with erenumab-aooe experienced a statistically significant reduction in migraine days (p-value <0.001). In study 1, participants receiving erenumab-aooe experienced reductions of 3.2 and 3.7 migraine days associated with 70 mg and 140 mg of erenumab-aooe respectively, compared to a reduction of 1.8 days in the placebo group. In study 2, participants receiving 70 mg of erenumab-aooe had 2.9 fewer migraine days compared to the 1.8 day reduction seen in the placebo group. Chronic migraine sufferers in both treatment groups of study 3 had 6.6 fewer migraine days compared with the 4.2 fewer migraine days associated with the placebo group.

Safety
Injection site reactions and constipation were the most common adverse reactions in clinical trials with greater frequency than placebo. The most common injection site reactions were pain, redness, and itching. It is possible for patients to develop anti-erenumab-aooe antibodies, which could neutralize its pharmacologic activity. Some participants in the studies demonstrated neutralizing antibody production.

Dosage
Erenumab-aooe is approved for use as once-monthly subcutaneous injections of 70 mg or 140 mg. The drug is available as a 70-mg preservative-free prefilled syringe and an autoinjector.

REFERENCES
Fix the Disconnect

Back in 1980 when I was attending pharmacy school at the University of Pittsburgh, I had dinner with Lewis Dittert, PhD, dean, and William E. Woods, who was then the executive vice president of the National Association of Retail Druggists, now known as the NCPA. During our dinner the discussion focused around better preparation for students to become pharmacists upon graduation.

I remember Dr. Dittert sharing a story about a preceptor who was irritated that the student pharmacist couldn’t change the tape in the cash register. Dr. Dittert explained that with all that needed to be taught with respect to pharmacology, pharmaceutics, and patient care, certainly the schools of pharmacy couldn’t be obligated to teach such a task as changing cash register tape. By the end of that dinner I learned the disconnect between practicing pharmacists and academia.

After practicing for 37 years, and precepting 60-plus students from four different institutions, I see that many of these sixth-year students aren’t prepared for practicing in the real world.

One skill set that our students seem to excel in is their ability to “look stuff up.” Unfortunately, this gives them the comfort that all they need to know can be found on their phones or tablets. In the real world such luxury is not practical. I tell students, “A physician will never consult you with a question that can be found on your phone. They have phones, too!”

We pharmacists need to have a working knowledge of therapeutics, after all that is our area of expertise. I understand that the education of our pharmacists has indeed shifted since I graduated 37 years ago. I realize students are not sitting in lecture halls with spiral bound notebooks, furiously drawing structures and writing notes from the professor’s chalkboard. However, I feel most students are totally unprepared especially when it comes to self-care (OTC) therapeutics. This is indeed the area that we pharmacists are expected to excel in.

“I feel most students are totally unprepared especially when it comes to self-care (OTC) therapeutics. This is indeed the area that we pharmacists are expected to excel in.”

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Fixing the disconnect means over 400 slides covering the ergot alkaloids. A headache specialist in Pittsburgh did a continuing education program 12 years ago and said, “Ergot alkaloids for migraine are hopelessly outdated.” As fun as history might be to teach, or even give background information on, 400 PowerPoint slides on therapeutics that went away over 20 years ago when triptans were introduced is a total waste of time. This time could be better allocated teaching our students more self-care (OTC) therapeutics, which most seem to be lacking in their clinical year. The two credit course that most schools have for self-care is not adequate given the plethora of OTC products now available.

I have a great deal of respect for those in academia. The most brilliant minds in the profession of pharmacy are in the hallowed halls of our schools of pharmacy. Unfortunately, most of these brilliant minds don’t spend any time in the community pharmacy practice, where most students eventually end up practicing. I’d like to see at least one practicing community pharmacist, as well as a hospital pharmacist, on every school of pharmacy’s curriculum committee.

I use the tagline on my business card “where academia and community pharmacy meet.” I blend academia and patient care in my 1200 square foot drug store. As a pharmacist passionate about the education of our students, I’d like to see more interaction between the schools of pharmacy and practicing community and hospital pharmacists. As our future students head back to school, I wish them success and a most beneficial year crammed full of information that will benefit their patients.
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