Pharmacy Today
An official publication of the American Pharmacists Association
DECEMBER 2023

COLLABORATE TO INNOVATE:

NEW DELIVERY MODELS, NEW WAYS PHARMACISTS PROVIDE CARE

CONTINUING PHARMACY EDUCATION
CPE
Updates to OTC products

PSYCHOTROPIC STEWARDSHIP
Medications for pediatric patients

CULTURAL COMPETENCE
Providing care to patients with disabilities

HCV
Pharmacists help build a model clinic

APhA

BulletinToday

Model cuts 5-year CVD event risk for Medicare patients

Results from a new study in *JAMA* found that the Million Hearts Model, which paid participating health care organizations to assess and reduce patients' CVD risk, decreased myocardial infarction and stroke rates for Medicare fee-for-service beneficiaries aged 40 to 79 years at high or medium risk for these events.

The Million Hearts Model, part of the broader Million Hearts initiative, is co-led by CDC and CMS and aims to prevent one million heart attacks and strokes over 5 years.

According to the study findings, the Million Hearts Cardiovascular Disease Risk Reduction Model reduced the probability of a first-time myocardial infarction or stroke over 5 years by 0.3%, and the probability of a first-time CVD event or CVD death by 0.4% for study participants when compared with the general population.

Researchers said the results support guideline recommendations for CV risk assessment.

In the trial, which ran from 2017 to 2021, patients with no previous myocardial infarctions or stroke and with high or medium CVD risk were enrolled from U.S.-based primary care and specialty practices, health centers, and hospital-based outpatient clinics. Organizations were assigned to a model intervention group or standard care control group. Of 516 organizations, 342 entered patients into the study population.

CVD-related Medicare spending in the intervention and control groups was similar, suggesting that paying for the intervention did not result in higher costs overall.

Using a novel longitudinal risk calculator, researchers noted that the model was unique in paying for overall CVD risk reduction rather than tying performance-based payments to control of individual risk factors.

The researchers said that the findings have implications for value-based payment policy.

"Systematic reviews show that value-based payment initiatives, both overall and for CVD care, have improved care processes, but few improved long-term outcomes. This randomized pragmatic trial suggests that paying for risk assessment and reduction could improve outcomes of public health importance. However, high rates of model nonparticipation demonstrate the importance of calibrating payments to effort and reducing burden of data sharing," the researchers wrote. ■

Pharmacies in Georgia gearing up to sell medical cannabis

Georgia is set to become the first state to allow independent pharmacies to sell medical cannabis. In early October 2023, the Georgia Board of Pharmacy began accepting over 120 applications from pharmacies who agreed to provide cannabis from one of the state's two licensed production companies.

Georgia's 2019 cannabis law allows independent pharmacists across Georgia to dispense cannabis oil to patients, without association of an approved producer. Georgia's legislature passed a bill in 2019 setting up a licensing process for companies to grow cannabis indoors under close supervision, convert the plant to oil, and sell the product to patients with a doctor's prescription if the companies are in a registry run by the Georgia Department of Public Health.

Patients will be able to buy cannabis oil at Georgia pharmacies if they show a state-issued low THC oil registry card and identification.

THC is the principal psychoactive compound of cannabis. Low THC oil can contain no more than 5% THC.

There are over 400 independent pharmacies in Georgia. Cannabis products are not being sold in chain community pharmacies. ■

DEA extends telehealth authorities for controlled substances through 2024

DEA will continue to allow providers to use telemedicine to prescribe certain controlled substances through the end of 2024.

DEA said the temporary authorization is designed "to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled medication prescriptions, as well as allowing adequate time for providers to come into compliance with any new standards or safeguards."

Controlled substances covered by the rule, which DEA released during the COVID-19 public health emergency, include stimulant medications for ADHD, anxiety, and OUD.

In May 2023, just before the expiration of the public health emergency, DEA said it would temporarily extend the telehealth flexibilities through November 11, 2023.

In September 2023, DEA hosted a listening session to hear from health care practitioners, experts, advocates, and patients who called on the agency to extend the more lenient rules and create a special registration pathway for remote prescribing. APhA took part in the listening session.

DEA said it hopes to draft new regulations by fall 2024.

The agency also announced a forthcoming proposed rule on telehealth prescribing of controlled substances, including buprenorphine, that will be released before the temporary rule expires on November 11, 2024. ■

Analysis finds e-prescribing by pharmacists on the rise, filling gaps in care

A new report from Surescripts finds that more pharmacists are electronically prescribing medications as they assist with managing chronic diseases for patients.

According to the report's data, the number of prescribers in the Surescripts' network who were not conventional primary care providers rose by 12.1% on average annually between 2018 to 2022, while the number of clinicians who frequently provide primary care grew by less than 1%.

Surescripts found that the number of overall e-prescriptions submitted by pharmacists increased by 47% between 2019 and 2022, in particular for drugs that treat chronic conditions. Electronic prescriptions for diabetes, high BP, and high cholesterol rose by 3.6% during that time frame, while the number of e-prescriptions in those categories submitted by conventional primary care providers fell by 3.5% on average each year.

"As gaps in primary care grow wider, pharmacists have become essential care providers—especially for patients with chronic conditions," said Frank Harvey, Surescripts CEO, in a press statement. "Health care has an opportunity to catch up by bringing policy and payment structures in line with how patients are accessing primary care and truly empowering pharmacists to deliver care at the top of their education and training and as part of a collaborative care team."

Additionally, Surescripts noted that a recent survey found 89% of prescribers and 97% of pharmacists support the increased use of team-based care. That survey found that 41% of prescribers believe it is essential for pharmacists to be able to issue prescriptions. ■

Metformin could be beneficial for gestational diabetes

The use of metformin among pregnant women with gestational diabetes was associated with enhanced glycemic control and reduced gestational weight gain, according to a randomized, placebo-controlled study published in *JAMA*.

The trial was conducted from June 2017 to September 2022 at two sites in Ireland, comprising 510 women with gestational diabetes.

The patients were randomly assigned to receive either a placebo or metformin with a maximum dose of 2,500 mg. Researchers at the University of Galway in Ireland found that the trial's primary outcome—a composite of insulin initiation or a fasting glucose of 5.1 mmol/L or higher at gestation weeks 32 or 38—did not differ notably between the two groups.

However, the women who used metformin were significantly less likely to require insulin and had considerably lower fasting blood glucose levels at weeks 32 and 38, the researchers found. There was a nonsignificant increase in babies that are small for their gestational age among the expectant parents using metformin. The researchers plan to follow up with mother and infant to see if those diagnosed as small for gestational age turn out to have an increase in BMI and weight as they grow into adolescents. ■

Telehealth can increase likelihood of remaining in OUD treatment

Initiating buprenorphine for OUD via telehealth enhanced patients' likelihood of staying in treatment longer compared with starting treatment in a nontelehealth setting, according to new research in *JAMA Network Open*.

The study was based on Medicaid data from 2019 to 2020 in Kentucky and Ohio. The researchers found that in Kentucky, 48% of those who started buprenorphine treatment through telehealth remained in treatment for 90 continuous days compared with 44% of those who started treatment in nontelehealth settings.

In Ohio, 32% of those who used telehealth to start buprenorphine remained in treatment for 90 continuous days compared with 28% of those who started treatment in nontelehealth settings.

The research was part of the HEALing Communities Study, the largest ever addiction prevention and treatment implementation study and backed by the National Institute on Drug Abuse (NIDA) in partnership with the Substance Abuse and Mental Health Services Administration and NIH's Helping to End Addiction Long-term Initiative.

"This study suggests that telehealth may increase treatment access and retention, strengthening the evidence that receiving addiction care through telehealth is to be safe and beneficial, and that it should be made available to those who need it," said Nora Volkow, MD, NIDA director, in a news release.

The study findings also indicated that receiving buprenorphine treatment through telehealth was not linked to a higher risk of nonfatal overdose. This finding suggests that patients were not adversely affected by having increased access to buprenorphine treatment through telemedicine. ■

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CPE

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Kelly L. Scolaro

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Take the Crossword Challenge

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Actions for today, hope for the future

The pharmacy profession is in the midst of a crisis. I frequently speak with student pharmacists and new graduates who are understandably concerned. Although each individual's situation is unique, there are a few things I share with these pharmacists in response.

First, be patient. APhA and other pharmacy associations are very aware of this plight and are advocating daily on your behalf with your employers and in Washington for regulatory and legislative change. It will not happen overnight, but I do believe change is coming and pharmacists' working conditions will improve. They must improve.

Second, use your voice. Join APhA and stay current with initiatives such as workplace well-being and advocacy for key issues like provider status through the Pharmacy and Medically Underserved Areas Enhancement Act.

Third, as much as you are able to, diversify your practice, innovate, and collaborate with others to take control of your workplace well-being.

This month's *Pharmacy Today* cover story provides examples of pharmacists who have innovated to create new practice models in community, consultant, specialty, health system, and other practices. For example, Jena Quinn, PharmD, owner of Perfecting Peds and her team of pediatric pharmacists serve children in long-term care, medical daycare, or home health to prevent pediatric polypharmacy. To demonstrate the value of the pediatric pharmacist, Quinn collected data on 1,355 pharmacist interventions and showed a decrease in hospital and emergency department admissions, fewer medications used, and a cost savings of nearly $500,000 annually.

In this issue of PT, you'll also find the latest on treating coughs and colds in children and whether or not ashwagandha can be a stress reliever. You'll learn the latest on pitfalls of online pharmacies, concerns about COVID-19 vaccine access, and collaborative practice agreements in the United States. Catch up on your CPE with this month's article on communicating with patients about OTC medications.

Are any of the actions I shared above going to change working conditions overnight? No, not even close. But until change comes—and it will come—know that your cries are being heard. APhA and others are working tirelessly for legislative, regulatory, and workplace changes. I encourage you to join APhA to strengthen these efforts, learn more about the progress we are making, and amplify your own voice. ■

Kristin Wiisanen
PharmD, FAPhA, FCCP
***Pharmacy Today* editor in chief**

Pharmacy's best days...

APhA held a student leadership event in Washington, DC, recently. The energy from 170 students in a room is contagious! I had the good fortune of talking with the group in a Q & A session, and the very first question was perhaps the most important one I've been asked in a long time.

"Dr. Hogue," said the student (and I paraphrase), "Constantly we hear about the difficult working conditions in pharmacies. We have pharmacists tell us they'd not choose this path again. We hear about the poor reimbursement for drugs. Pharmacy schools are not filling their classes. Yet as we've interacted with you, you seem to have optimism for something in the future. Where does your hope come from?"

Boom! There it was! The question of questions. The ONE question that every pharmacist who pauses long enough to take a breath must ask themselves. The ONE question that drives us to persevere through challenges. The ONE question that allows us to contemplate tomorrow. It's the ONE and only question that truly, at its core, makes even the toughest day bearable. Hope. A simple four-letter word.

I have hope, and so should you. Yes, I'm in touch with reality. Yes, I know things have been bad. But I have hope things will get better. And I have evidence that they will. "Good," you say! "It's about time someone tells me what there is to be hopeful for!" I say, "Come on! You've already got it in you!" And then I smile. Let's sit and talk about it, shall we?

I have hope because I know that I am on this planet to make it a better place. I have hope because I have a purpose, and my purpose is to relieve suffering and be used as an instrument of healing. My guess is that's why you became a pharmacist, too. As APhA CEO, part of my job is to help you see that hope.

We should have hope because there is a world in tremendous pain that needs us to lean in and provide care. And the pandemic, while causing a lot of pain, has given me even greater hope for the future of our profession.

For the first time in my career, I'm hearing patients and patient advocacy groups actually lobbying state legislatures and Congress for access to their pharmacists. I'm watching as a physician assembly member in California champions a new law that requires payment for pharmacist's services at the same rate as physician providers. I'm seeing those OUTSIDE of our profession truly value our profession and what we do. This is unprecedented! Pharmacists are breaking through!

I'm also seeing pharmacists in local communities stand up for their trusted patient relationships. Pharmacists who are saying they've had enough with inadequate staffing, inadequate technical support, poor reimbursements, and those who are unkind.

These pharmacists are standing up and saying, "NO! My patients matter! My health matters!" And the result is that change is in the wind. Employers are listening. Patients are watching. Regulators are acting. Everyone recognizes with crystal clarity that the pharmacist–patient relationship is a bond that must be preserved and can't be broken. Patients don't want to lose their access to local pharmacists and they are getting involved, too.

While you may not see it happening as fast as we all want, it really is happening. Technicians are being elevated in responsibility to truly be the assistant pharmacists need. Payers are recognizing that pharmacists do more than put pills in bottles, and policymakers are quickly moving to provide compensation for our care services. Fundamentally, the entire way that consumers access a pharmacist, receive their medicines, and access health care in general is changing—but we've got to first go through the transformation of change, and it's not an easy journey.

So today, like every day, I look ahead to where we are going and all the opportunities in front of our profession. Getting to it is a struggle. Change is hard. But this profession is worth fighting for. This hope is real, and our patients need us to keep pressing on.

I know where my hope comes from. I'm betting you do, too. Dig deep. It's there. Embrace it. Chase it. Persevere through the challenges. I see you. APhA is with you. Pharmacy's brightest days are yet to come.

For every pharmacist. For all of pharmacy. ■

Michael D. Hogue
PharmD, FAPhA, FNAP, FFIP
Executive vice president and CEO of APhA

NEW DRUGS

ETRASIMOD
(Velsipity—Pfizer Inc.)

Drug class: Velsipity is a sphingosine 1-phosphate receptor modulator.

Indication: Velsipity is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

Recommended dosage and administration: Assessments are required prior to initiating Velsipity. The recommended dosage is 2 mg orally once daily.

Common adverse effects: The most common adverse reactions are headache, elevated liver levels, and dizziness.

Warnings and precautions: Velsipity is contraindicated in patients who have experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months. It is also contraindicated for those with a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

Velsipity may increase the risk of infections. Obtain a complete blood count before initiation of treatment. Monitor for infection during treatment and for 5 weeks after discontinuation. Consider interruption of treatment if a serious infection develops. Avoid use of live attenuated vaccines during and for up to 5 weeks after treatment. Treatment with Velsipity may result in a transient decrease in heart rate and AV conduction delays. Obtain an ECG to assess for preexisting cardiac conduction abnormalities before starting treatment. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate. Elevations of transaminases may occur. Obtain transaminase and bilirubin levels before initiating Velsipity. Discontinue if significant liver injury is confirmed.

Velsipity may increase the risk of macular edema. Obtain a baseline evaluation of the fundus, including the macula, near the start of treatment. Periodically conduct an evaluation of the fundus, including the macula, while on therapy and any time there is a change in vision. Consider discontinuing Velsipity if macular edema develops. Monitor BP during treatment. Velsipity may cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 1 week after stopping Velsipity. Obtain a skin examination prior to or shortly after the start of treatment and periodically during treatment, especially if risk factors are present. Promptly evaluate suspicious skin lesions. If symptoms of posterior reversible encephalopathy syndrome develop, obtain a physical and neurological exam, and consider MRI. Velsipity may cause a decline in pulmonary function. Assess pulmonary function if clinically indicated. Consider the half-life and mode of action of prior therapies as unintended additive immune system effects from prior treatment with immunosuppressive or immune-modulating drugs may occur. If using concomitant immunosuppressants, monitor patients for infectious complications for up to 5 weeks after the last dose of Velsipity. Use is not recommended in severe hepatic impairment.

ZILUCOPLAN
(Zilbrysq—UCB Inc.)

Drug class: Zilbrysq is a complement inhibitor.

Indication: Zilbrysq is indicated for the treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive.

Recommended dosage and administration: Obtain baseline amylase and lipase. Zilbrysq should be administered by S.C. injection only. The recommended dosage is 16.6 mg in patients who weigh <56 kg, 23 mg in patients who weigh 56 kg to <77 kg, and 32.4 mg in patients who weigh ≥77 kg.

Common adverse effects: The most common adverse reactions were injection site reactions, upper respiratory tract infection, and diarrhea.

Boxed warning: Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Complete or update meningococcal vaccination at least 2 weeks prior to administering the first dose of Zilbrysq unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection. Comply with the most current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor. Persons receiving Zilbrysq are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected. Zilbrysq is only available through a restricted program called REMS.

Other warnings and precautions: Zilbrysq is contraindicated in patients with unresolved *N. meningitidis* infection. Use caution when administering Zilbrysq to patients with any other systemic infection. Pancreatitis and pancreatic cysts have been reported in patients treated with Zilbrysq. Discontinue Zilbrysq in patients with suspected pancreatitis and initiate appropriate management until pancreatis is ruled out or has resolved. Use in pregnancy may cause fetal harm.

NEW FORMULATIONS

ACETAMINOPHEN AND IBUPROFEN
(Combogesic I.V.—AFT Pharmaceuticals)

Drug class: Acetaminophen is a nonopiate, nonsalicylate analgesic. Ibuprofen is an NSAID.

Indication: Combogesic I.V. is indicated in adults where an I.V. route of administration is clinically necessary for the relief of mild to moderate pain or the management of moderate to severe pain as an adjunct to opioid analgesics. Combogesic I.V. is indicated for short-term use of 5 days or fewer.

Recommended dosage and administration: The lowest effective dosage for the shortest duration consistent

with individual patient treatment goals should be used. Do not exceed the maximum total daily dose of Combogesic I.V. (4,000 mg acetaminophen and 1,200 mg ibuprofen) in 24 hours. Do not exceed a total daily dose of 4,000 mg of acetaminophen from all sources. Do not administer with other acetaminophen-containing products. For adult patients weighing ≥50 kg (actual body weight), the recommended dosage is 1,000 mg of acetaminophen and 300 mg of ibuprofen administered as a 15-minute infusion every 6 hours, as necessary. For adult patients weighing <50 kg (actual body weight), the recommended dosage is 15 mg/kg acetaminophen and 4.5 mg/kg ibuprofen administered as a 15-minute infusion every 6 hours, as necessary.

Common adverse effects: The most common adverse reactions are infusion site pain, nausea, constipation, dizziness, infusion site extravasation, vomiting, headache, and somnolence.

Boxed warning: Take care when prescribing, preparing, and administering Combogesic I.V. to avoid dosing errors, which could result in accidental overdose and death. Combogesic I.V. contains acetaminophen, which has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with doses of acetaminophen that exceed 4,000 mg per day, and often involve more than one acetaminophen-containing product. NSAIDs, such as the ibuprofen in Combogesic I.V., may cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Combogesic I.V. is contraindicated in the setting of coronary artery bypass graft (CABG) surgery. NSAIDs, such as the ibuprofen in Combogesic I.V., cause an increased risk of serious GI adverse events, including bleeding, ulcerations, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and those with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Other warnings and precautions: Combogesic I.V. is contraindicated in patients who have previously demonstrated hypersensitivity to acetaminophen, ibuprofen, other NSAIDs, or to any of the excipients in the I.V. formulation, patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs, patients with severe hepatic impairment or severe active liver disease, and in the setting of CABG surgery. Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs.

Monitor BP. Avoid use of Combogesic I.V. in patients with severe heart failure unless benefits are expected to outweigh risks of worsening heart failure. Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Discontinue use immediately if anaphylactic symptoms occur. Combogesic I.V. is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with pre-existing asthma. Discontinue Combogesic I.V. at first appearance of skin rash or other signs of hypersensitivity. If a drug rash with eosinophilia and systemic symptoms occurs, discontinue treatment and evaluate clinically. Limit use of NSAID-containing products between about 20 weeks to 30 weeks in pregnancy due to the risk of oligohydramnios/fetal renal dysfunction. Avoid use of NSAID-containing products at about 30 weeks' gestation and later in pregnancy due to the risks of oligohydramnios/fetal renal dysfunction and premature closure of the fetal ductus arteriosus. Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia. Combogesic I.V. is not recommended in patients with renal or hepatic impairment. A number of known or potential interactions between Combogesic I.V. and other drugs/drug classes exist.

NEW COMBINATIONS

CLINDAMYCIN PHOSPHATE, ADAPALENE, AND BENZOYL PEROXIDE
(Cabtreo—Bausch Health)

Drug class: Cabtreo is a combination of a lincosamide antibacterial, a retinoid, and benzoyl peroxide.

Indication: Cabtreo is indicated for the topical treatment of acne vulgaris in adult and pediatric patients 12 years and older.

Recommended dosage and administration: Apply a thin layer of Cabtreo to the affected areas once daily. Avoid the eyes, mouth, paranasal creases, mucous membranes, and areas of broken, eczematous, or sunburned skin. Cabtreo is not for oral, ophthalmic, or intravaginal use.

Common adverse effects: The most common adverse reactions were application site reactions, pain, erythema, dryness, irritation, exfoliation, and dermatitis.

Warnings and precautions: Cabtreo is contraindicated in known hypersensitivity to clindamycin, adapalene, benzoyl peroxide, and components of the formulation or lincomycin, and history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis. If a serious hypersensitivity reaction occurs, discontinue Cabtreo immediately and initiate appropriate therapy. Clindamycin can cause severe colitis, which may result in death. Discontinue Cabtreo if diarrhea occurs. Avoid or minimize exposure to sunlight and sunlamps. Wear sunscreen and protective clothing when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/burning, and irritant and allergic contact dermatitis may occur with use of Cabtreo and may necessitate discontinuation. Use Cabtreo with caution in patients receiving neuromuscular blocking agents. ■

The dos and don'ts of treating kids' colds and coughs

Mary Warner

As any parent or teacher knows, children of all ages are likely to catch a cold at least once over the course of cold and flu season, whether from their siblings, neighborhood friends, or classmates. Most colds don't cause serious complications, but they do cause parents and other caregivers to worry. According to FDA, most children will get better without any medication, and in fact, cough or cold medicines won't make a cold go away any faster.

Age matters

When treating colds and coughs, age really does matter. Infants and children under 2 years old should not be given any kind of cough and cold product that contains a decongestant or antihistamine because serious adverse effects, including convulsions, rapid heart rates, and even death could occur. Manufacturers of pediatric cough and cold medications voluntarily label these products to state that they should not be used for children under 4 years old.

However, in older children, OTC cough and cold medications can help reduce the discomfort caused by a cold by treating symptoms such as a runny nose, nasal congestion, and cough. Because symptoms will usually resolve themselves without treatment, cough and cold medications are best used when the symptoms are too uncomfortable or make it difficult for the child to breathe or sleep.

An OTC pain reliever such as acetaminophen or ibuprofen can reduce a fever and ease the pain of a sore throat. Dosing guidelines should be followed carefully, especially for small children. Children under 3 months old should not be given acetaminophen unless advised by a pediatrician; ibuprofen should not be given to a child younger than 6 months old or to children who are vomiting or are dehydrated.

Caution should be used when giving aspirin to children or teenagers. Although aspirin is approved for use with children older than 3 years, it has been linked to Reye's syndrome, a rare but potentially life-threatening condition when given to children recovering from chickenpox or flu-like symptoms.

Dosing

Before giving any medication to a child, parents and caregivers should carefully read the information on the Drug Facts label or talk to their pediatrician or pharmacist about dosing information. Nonprescription cough and cold products can be harmful to children if they are given more than the recommended dose or are given the medicine too often, or if they are given more than one product containing the same medication (such as acetaminophen in a pain medication and in a cold medication). Children should never be given medications that are packaged and intended for adults.

To ensure that the correct dose is given to the child, FDA encourages manufacturers to provide a dosing container, such as a syringe or a cup, marked with the correct measurements with all oral liquid medications. If a medication doesn't come with a measuring device, parents or caregivers can purchase droppers and syringes with appropriate measurements in the pharmacy. Other containers, such as household spoons, should never be used to measure medications for children.

Alternative relief

FDA offers several tips for relieving cough and cold symptoms in infants and children:

- A cool mist humidifier makes breathing easier by decreasing congestion in nasal passages. However, warm mist humidifiers should not be used because they can cause nasal passages to swell and make breathing more difficult.
- Saline nose drops or sprays keep nasal passages moist and help avoid stuffiness.
- Nasal suctioning with a bulb syringe or a similar product, with or without saline nose drops, works very well for children younger than a year old.
- Encourage children to drink plenty of liquids to stay hydrated.

Homeopathic products

Cough and cold medications advertised as homeopathic are intended to mitigate cold symptoms but may look similar to dietary supplements. They are not approved by FDA and should be used with caution, as FDA has found that some of these products contain active drug ingredients in levels that far exceed the amount stated on the product's label and could cause significant harm to children. FDA states that it is not aware of any proven benefits from homeopathic cough and cold products and urges parents and caregivers to avoid these products, especially for children younger than 4 years old.

What to tell your patients

Advise patients that colds and coughs are a normal part of childhood and will generally resolve with rest. Advise them to consult with their pediatrician if a child has a fever of 102°F or higher, a fever of 100.4°F or higher in an infant 2 months or younger, blue lips, labored breathing, signs of dehydration, excessive sleepiness, or persistent ear pain. ■

Can ashwagandha soothe stress?

Mickie Cathers

As health concerns over anxiety and stress levels have grown in recent years, sales of ashwagandha have also soared as demand spiked for supplements addressing mood and stress. Sold as a mood enhancer, relaxant, and stress reliever, this supplement has consumer reviewers saying they "can't live without it."

Background

Ashwagandha's Latin name, *Withania somnifera,* means "sleep-inducing" and highlights the plant's reputation of having calming effects. *Ashwagandha* is a small perennial shrub with yellow flowers and is a member of the nightshade family related to potatoes and tomatoes. The plant is native to southern Asia and northern Africa and has been used for thousands of years in ayurvedic medicine to improve fatigue, mood, sleep, and libido.

Ashwagandha root extract has been shown to have gamma-aminobutyric acid–mimetic activity and its bioactive compounds include amino acids, alkaloids (withanine, withasomnin), lactones (withanolides), and glycosides (sitoindosides). Antiangiogenic properties that inhibit inflammation and tumor growth are derived from high concentrations of withanolides found in ashwagandha root extract.

Is there a benefit?

Ashwagandha has recently been promoted for its positive impact on serotonin receptors, thereby helping to suppress stress-induced increases of dopamine receptors in the brain and decreasing cortisol levels. Ashwagandha has been recognized as an adaptogen and, although their effectiveness is controversial, adaptogens' stress-protective activity has been linked with the hypothalamic-pituitary-adrenal axis and the regulation of key mediators of stress response.

Recent studies have shown similar, if slightly mixed, results. Smith and colleagues explored the efficacy and safety of ashwagandha root extract on stress, fatigue, and sex hormones in overweight or mildly obese patients with self-reported stress and fatigue.

Published online September 23, 2023, in the *Journal of Psychopharmacology*, this randomized, double-blind, placebo-controlled trial ran for 12 weeks. Patients aged 40 years to 75 years supplemented with 200 mg of ashwagandha root extract or placebo twice daily. Results showed that ashwagandha was associated with a significant reduction in stress levels; however, the improvements were not significantly different compared with the placebo group.

Two 2022 double-blind, randomized, placebo-controlled trials published in the December issue of the *Journal of Medicinal Food* studied ashwagandha's effects in the same population of 60 college students who were 18 years to 50 years old. Baker and colleagues evaluated the outcomes of 4 weeks of ashwagandha supplementation on stress, anxiety, depression, and a feeling of overwhelm and exhaustion, randomized to either the intervention (700 mg ashwagandha root extract) or a placebo (glycerol). Findings demonstrated that ashwagandha increased perceived well-being by supporting sustained energy, heightened mental clarity, and enhanced sleep quality.

Meanwhile, O'Connor and colleagues investigated the impact of ashwagandha on stress and sleep quality and found a significant positive impact on reducing stress and improving sleep quality. This study saw more pronounced stress differences at 6 weeks of supplementation, indicating that ashwagandha may require a longer time period of use to show stress-relieving differences.

Availability

Ashwagandha is available as gummies, powders, tablets, liquids, and capsules and is often paired with black pepper to aid absorption and digestion. This supplement can be found on market shelves and online in various dosages ranging from 200 mg to 4,500 mg capsules.

What to tell your patients

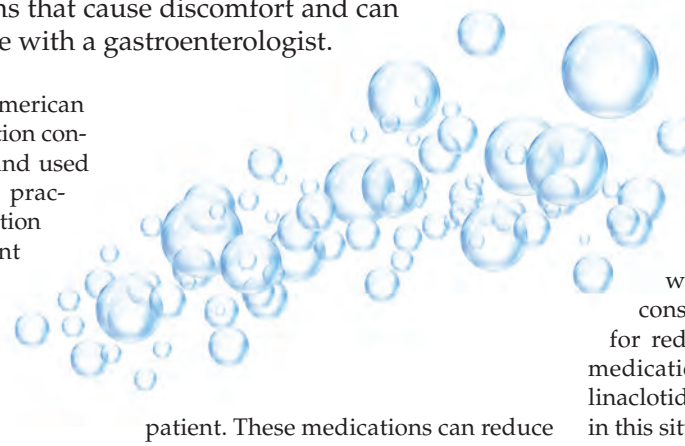
Ashwagandha is well-known for its anti-inflammatory activity and may help with fatigue and sleep issues, indirectly affecting stress and anxiety. Inform patients who are interested in taking ashwagandha that this supplement is considered safe for most people with limited reports of adverse effects at dosages of 400 mg to 700 mg tablets per day. Extremely high dosages can cause upset stomach, diarrhea, and vomiting.

Caution pregnant or breastfeeding patients as well as those with lupus, rheumatoid arthritis, T1D, and Hashimoto's disease to avoid using ashwagandha. Ashwagandha may interact with thyroid, blood sugar, and BP medication. ■

Experts release best practices for management of belching, abdominal bloating, and distention

Olivia C. Welter, PharmD

For many people, GI issues can cause significant disruptions to their daily lives. Belching, abdominal bloating, and distention are some of the primary symptoms that cause discomfort and can lead patients to seek care with a gastroenterologist.



With this in mind, the American Gastroenterological Association conducted a literature review and used the results to develop best practices for pathology identification and symptom management of belching, bloating, and abdominal distention. The results were published in *Gastroenterology* on July 13, 2023.

Best practice highlights

Moshiree and colleagues published a total of 15 best practice advice statements. Many of the statements are related to screening, diagnostic testing, and behavioral treatment options. Some statements suggest potential for pharmacist involvement in resolving their patients' abdominal issues with medication therapy and management, which are summarized below.

As stated by authors, "a multidisciplinary approach and a patient-centered model are keys to managing treatment in patients with belching, abdominal bloating, and distention."

Central neuromodulators

One such medication type that can be used to offer relief of certain gastric symptoms is central neuromodulators. The investigators noted that TCAs and SNRIs show the greatest relief for these symptoms.

The reasoning behind this treatment option is that central neuromodulators can help reduce psychological stress, as this type of stress can cause belching. Central neuromodulators can also raise the symptom threshold for bloating, which means the body can withstand more of the symptom before it becomes an issue for the patient. These medications can reduce visceral hypersensitivity and therefore minimize pain or discomfort felt in visceral organs like the stomach.

In patients who experience belching, central neuromodulators are most effective when combined with other therapies. Specifically, brain–gut behavioral therapies like relaxation training and gut-directed hypnotherapy can be part of the equation for improving patients' symptom burden and, subsequently, quality of life.

Clinicians can also consider central neuromodulators for patients when bloating and distention are problematic symptoms. According to the researchers, sensations of bloating and distention may be exacerbated when patients have comorbid psychological symptoms like depression or anxiety, making antidepressants an appropriate treatment choice. Existing literature and the authors' clinical experiences demonstrate that central neuromodulators may have the most benefit in patients with irritable bowel disease (IBS) and patients who experience distention after a meal.

Probiotics

The study authors do not recommend treating bloating or distention with probiotics. Though this option may seem appealing on the surface, guidelines established in the United States, England, and Europe for management of IBS and functional dyspepsia do not explicitly endorse using probiotics for global symptom treatment. In fact, researchers noted that the risk of adverse effects like brain fogginess and lactic acidosis could outweigh any benefit of probiotics.

Gut-related medications

Often, symptoms like belching, abdominal bloating, and distention can exist comorbidly with constipation. This is especially common for patients with IBS. Medications that treat constipation can also be effective for reducing bloating. Prescription medications including lubiprostone, linaclotide, and tepanor may be used in this situation.

Antibiotics

Sometimes, gastric issues can be caused by small intestine bacterial overgrowth. Though clinicians sometimes use empiric antibiotic therapy in patients with bloating, the authors warn that antibiotics are not approved by FDA to treat belching or bloating. For this reason, patients must be carefully selected for antibiotic therapy; providers can look for chronic watery diarrhea, signs of malnutrition and weight loss, and diseases like cystic fibrosis and Parkinson disease when deciding whether a patient would qualify for diagnostic testing or empiric antibiotic treatment.

Background

After reviewing the published literature, including clinical trials, robust observational studies, and expert opinions, the authors noted that their advice statements do not carry formal ratings regarding quality of evidence or strength of the presented considerations. Additionally, they noted a lack of existing literature investigating the pathophysiology and risk factors of belching and bloating, meaning providers don't have much evidence to use when making treatment decisions. ■

Gastrointestinal bleeding from low-dose aspirin may increase risk of anemia in older adults

Clarissa Chan, PharmD

Results from the ASPREE randomized, double-blind clinical trial, which were published in the July 2023 issue of the *Annals of Internal Medicine*, validated the concept that aspirin at low doses may cause damage to the GI tract.

Low-dose aspirin is an effective medication for the prevention of CVD. Typically, low-dose translates to 75 mg to 100 mg of aspirin daily, depending on the country. However, even at these low doses, aspirin use is not without risk.

Study design and findings

The ASPREE trial included 19,114 people aged 65 years or older from the United States and Australia. Over an average treatment period of 4.5 years, taking a 100-mg dose of aspirin each day was associated with a 20% higher risk of anemia compared with taking a placebo.

Aspirin's benefits for prevention of CVD far outweigh its GI risk.

For every 1,000 people followed for a year, there were 51.2 cases of anemia in the aspirin group and 42.9 cases of anemia in the placebo group. Over 5 years, hemoglobin (Hgb) concentrations declined by 3.6 g/L and 4.2 g/L in the placebo and aspirin groups, respectively.

Of the 7,139 participants for whom baseline and year 3 ferritin levels were measured, the aspirin group had increased prevalence of ferritin levels of less than 45 µg/L at year 3 (465 [13%] aspirin group participants vs. 350 [9.8%] placebo group participants) and greater overall decline in ferritin levels (by 11.5%) than the placebo group.

Dosing issues

Aspirin's benefits for prevention of CVD and strokes far outweigh its GI risk, according to Byron Cryer, MD, a gastroenterologist and chair of internal medicine at Baylor University Medical Center in Dallas. "Aspirin should definitely not be withheld because of the phenomenon of GI blood loss," said Cryer.

In this context, it is far more important to protect the heart and brain at the expense of the GI tract, as GI morbidity and mortality derived from long-term use of low-dose aspirin is much less than the CV morbidity and mortality that arise when aspirin is withheld, he said.

Cryer has studied the GI effects of low-dose aspirin over many years.

He previously conducted a prospective dose-finding study with aspirin to endoscopically assess whether there might be an orally administered dose of aspirin that wouldn't include GI adverse effects.

"In that study, we found that aspirin doses as low as 10 mg daily cause gastric ulcers," said Cryer.

Another caveat is that 10 mg is suboptimal for platelet inhibition. Thus, there is likely no orally administered aspirin dose that is an effective antiplatelet agent and is without GI adverse effects, Cryer said.

Preventing GI bleeds

Because many patients will need to take aspirin for CV and cerebrovascular benefits, some new strategies may decrease the incidence of GI bleeding.

There has been a great deal of focus in drug development for two decades around this issue of aspirin-associated GI blood loss. One approach has been PPI-aspirin combination or PPI coadministration with aspirin.

However, a PPI only protects against aspirin-GI blood losses in the proximal GI tract and does not protect against the greater component of more extensive small intestinal and colonic blood losses, according to Cryer.

"Another approach that has been recently commercially developed to reduce GI injury is Vazalore (81 mg and 325 mg aspirin), a newly introduced OTC aspirin–lipid formulated capsule," Cryer said.

Monitoring GI blood loss

How should GI blood loss be monitored in patients taking long-term, low-dose aspirin who are at high risk for aspirin-induced GI bleeding?

"Regarding the time interval that Hgb should be followed, that has not yet been defined by guidelines and will likely be individualized," said Cryer. "However, until guideline assistance is developed, Hgb assessment intervals somewhere in the range of 3 to 12 months seem reasonable."

Cryer stated that the ASPREE trial is a large prospective trial that validates what has been observed with low doses of aspirin in smaller studies for many years.

"Anemia in older people—likely caused by aspirin-induced GI bleeding—is tied to functional decline, fatigue, and higher mortality," said Cryer. "The findings therefore reinforce new guidelines that promote aspirin as a tool for secondary—not primary—prevention of CVD in older people and support regular monitoring of hemoglobin in patients who use the drug." ■

The case for psychotropic stewardship as more youth prescribed medication

Loren Bonner

Roughly 12% of pediatric patients are prescribed psychotropic medications, with vulnerable populations—such as those in foster care—prescribed these medications at even higher rates.

"With COVID-19, we've seen prescribing rates of certain medication classes, like stimulants and antidepressants, go up, too," said Danielle Stutzman, PharmD, BCPP, a psychiatric pharmacist at Children's Hospital Colorado and lead author of a paper published September 13, 2023, in the *Journal of the American College of Clinical Pharmacy* about the role of board-certified psychiatric pharmacists (BCPPs) in child and adolescent psychiatry. "COVID-19 really harmed the pediatric population."

During the pandemic, the American Academy of Child and Adolescent Psychiatry (AACAP), the American Academy of Pediatrics, and the Children's Hospital Association declared a national emergency in child and adolescent mental health. The U.S. Surgeon General issued an advisory, too.

An added layer to the crisis is that child and adolescent psychiatrists are in short supply, with a national average of only 14 child and adolescent psychiatrists per 100,000 children, according to AACAP.

But within all the complexity of this, psychotropic stewardship is emerging as a recognized model, with BCPPs playing an essential role in medication management on interdisciplinary psychiatry teams.

"Our goal and our paper, as well as other initiatives, is to encourage psychotropic stewardship as a model in which BCPPs can play a role in medication management on the psychiatric team and a role in mitigating the provider shortage," said Stutzman.

The ultimate goal of psychotropic stewardship is for every patient with a psychiatric disorder to have their medication therapy reviewed, optimized, and managed by a psychiatric pharmacist as part of a psychotropic stewardship team.

Defining psychotropic stewardship

The American Association of Psychiatric Pharmacists (AAPP) is promoting the expansion of psychiatric pharmacy through the development of psychotropic stewardship programs. In a paper published April 12, 2023, in *Mental Health Clinician*, researchers define what psychotropic stewardship is—and its purpose.

Similar to antimicrobial stewardship, the authors wrote, psychotropic stewardship promotes the safe and appropriate use of psychotropic medications, minimizes unintended consequences, and improves patient outcomes.

"AAPP envisions every patient with a psychiatric diagnosis will have their medication treatment plan reviewed, optimized, and managed by a psychotropic stewardship team with a psychiatric pharmacist as a co-leader," researchers wrote.

AAPP and others want psychotropic stewardship to be officially recognized by regulatory agencies as a standard of care for patients who receive a diagnosis of a psychiatric disorder or SUD.

"Like antimicrobial stewardship, [psychotropic stewardship] would allow payment services going forward," said Robert Haight, PharmD, BCPP, corresponding author of the paper and a clinical pharmacist at Minnesota Department of Human Services.

Lauren Leiby, PharmD, BCPP, a behavioral health patient care pharmacist at Nationwide Children's Hospital in Columbus, OH, sees the paper by Haight and colleagues as a "call to action."

Everyday practice

"Stewardship is what I do every day," said Leiby, who was a coauthor on the recent *JACCP* paper about the role of BCPPs in child and adolescent psychiatry. "Much like antimicrobial stewardship aims at preventing antibiotic resistance, psychotropic stewardship for youth helps ensure they have positive outcomes in the future if we can optimize medications now."

Stutzman also recognizes the importance of early intervention for young psychiatric patients. For example, a BCPP pharmacist can help a psychiatrist use clozapine for an adolescent with severe mental illness or early schizophrenia. "That's a life-changing intervention early on," said Stutzman.

Specifically, she said she supports the provider to feel comfortable using clozapine—an effective medication, but also one with adverse effects to be aware of. Stutzman will collaborate with the provider on titration of the medication and on the drug monitoring plan.

Other duties include navigating the REMS program and educating the patient and their family. ■

Addressing stimulant shortages

According to the most recent data from CDC, which was released in 2016, 62% of U.S. children diagnosed with ADHD were taking medication for ADHD. This represents 1 out of 20 of all U.S. children.

Danielle Stutzman, PharmD, BCPP, a psychiatric pharmacist at Children's Hospital Colorado, as well as many other clinicians working in behavioral health, have struggled to get patients their medications because of the ongoing stimulant shortage in the United States.

Stutzman and colleagues created a toolkit for pharmacists and other clinicians, which provides an evidence-based guide for thoughtfully converting from one stimulant product formulation to another.

"We don't want to tell families they have to go without medication," said Stutzman.

Visit https://aapp.org/guideline/stimulant to access the toolkit.■

ON THE COVER

COLLABORATE TO INNOVATE

New delivery models offer trailblazing ways pharmacists provide care

Loren Bonner

For years, some pharmacists have been working in collaboration with health care providers in models that generate revenue through the delivery of various Medicare services. The most common example of this is pharmacists who deliver chronic care management (CCM) services to patients who meet the qualifications. This includes CCM, which are non–face-to-face visits, as well as in person transitional care management services and annual wellness visits, all reimbursed by Medicare. Pharmacists working in these ways are usually directly employed by a physician practice as a full-time employee and often share in the revenue created from these services.

But this delivery model may just be a taste of what could be possible when pharmacists and health care providers collaborate. Three pharmacists profiled in this story are working collaboratively with providers—but in new ways. Their stories are a testament to what pharmacists are capable of and what they should be paid for.

Jaron Stout, PharmD

Jaron Stout, PharmD, is shaking up the model of consultant pharmacy in nursing homes.

"It has to change," said Stout, who has worked as a consultant pharmacist in Utah for over 12 years.

CMS regulations from 2018 state that 66% of medication-related adverse events in nursing homes are preventable. Two of the most common medication-related adverse events are related to anticoagulation and diabetes—the "bread and butter for consultants," according to Stout.

Jaron Stout, PharmD

"Consultant pharmacists are missing the mark because that is unacceptable," said Stout.

CMS regulations require that every skilled nursing facility employs a consultant pharmacist to review residents' medication every month. But, Stout said, consultant pharmacists should be doing more than checking a box to say they looked at a patient's medications. "It's unfortunately a lot of compliance checks to make sure the [facility] is in line with regulations instead of 'here are things we can address with your medications,'" he said.

Stout is working to deliver better care to nursing home patients through collaborative practice agreements (CPAs).

"When I came across collaborative practice agreements, that's when things changed for me," said Stout. "I met with an attorney, wrote a CPA, and started my own company."

Stout currently has CPAs with roughly eight different physicians or medical groups.

"The benefit of a CPA is that instead of me leaving [the facility] a stack of paperwork to take care of, it's me giving them the stack and saying here's the stuff that's been discussed with your physician and preapproved," said Stout. "Eventually, and ideally, it will turn into a report saying here's the stuff I did fix while I was here, and it's all done for you."

CPAs have different requirements depending on the state. In a nursing facility or a skilled nursing facility, they are under federal regulations and are thus limited. Current federal regulations specify who can write an order, and pharmacists are not included in that language. However, physicians may delegate writing orders to a therapist for therapy and to a dietitian for diet. Currently, those are the only two situations that can be delegated.

"We need to add pharmacists operating under a collaborative practice agreement to the list of professionals who can be delegated the task of writing orders," said Stout. He's created a coalition to get CMS to recognize pharmacists under CPAs to write orders in nursing homes.

Regulations also specify that signing orders, which is different from writing orders, can be handled according to state laws and regulations. "I've discussed the difference between writing and signing orders with my health care attorney. We both concluded that signing orders is likely for routine day-to-day orders, but writing orders will be generating an entirely new order from scratch," said Stout.

Stout also performs CCM services through incident-to billing and has recently started doing behavioral health integration, which functions like CCM but is centered around behavioral health. He plans to do annual wellness visits in the near future. Stout can perform and get paid for these services as an employee (i.e., with a W-2 or 1099) of a medical group—essentially services performed under a business agreement, which is different from a CPA.

"Pharmacists have two problems. We can't write orders, and we cannot bill for our time," said Stout. "Physicians can delegate to us their ability to write orders through a collaborative practice agreement. They can also delegate their ability to bill for their time through a business agreement."

"When I came across collaborative practice agreements, that's when things changed for me."

The long-term goal and vision for consultant pharmacists, in Stout's view, is to be a service provided by the medical director. This means, consultant pharmacists work under CPAs and are able to perform billable services. It also means that instead of one consultant pharmacist overseeing 12 to 15 homes, they go to 3 to 5 homes and have a greater impact with a smaller patient load.

"Pharmacists want provider status, but rather sit and wait for it to happen, I think we should use the tools and resources that CMS has given us to prove ourselves," Stout said. "There are tons of opportunities in long-term care that we can use as stepping stones to provider status."

Stout even noted that CMS has asked the attorney of his coalition why they haven't used any of these opportunities before.

Ana Simonyan, PharmD

Ana Simonyan, PharmD

Most pharmacists will independently manage a patient's chronic disease state when working collaboratively in primary care or other settings. But in integrated health-system specialty pharmacy, pharmacists work as part of the team on a patient's care plan.

"The integrated specialty pharmacy model is unique in that pharmacists are present in the clinic space to see patients, to interface with providers, to provide counseling, but also to have access on the back end to the pharmacy dispensing software, to the prior authorization and appeals information," said Ana Simonyan, PharmD, a clinical pharmacy specialist in Vanderbilt's infectious diseases clinic as well as a clinical team lead for Vanderbilt Specialty Pharmacy.

Simonyan has a CPA in place with prescribers in her clinic. "We are perfectly positioned to not only have an idea of what the provider wants, but also what the payer wants," said Simonyan.

In general, most specialty medications require prior authorization or some additional step needed for approval. Simonyan assists with that—usually with the help of a pharmacy technician—and navigates all financial aspects for the patient.

More than 40 pharmacists span 20 different specialized clinics within Vanderbilt. For Vanderbilt's infectious disease clinic, Simonyan is the only pharmacist

dedicated to the space, along with a technician. Floaters also come through.

On a typical day in the clinic, Simonyan will see a patient alongside the provider, either before or after the provider has seen the patient. During a warm handoff, Simonyan will talk to the patient and caregiver about what to expect after the visit. This can include everything from labs to the process for getting the patient's medication approved.

Once all the relevant clinical information is received, Simonyan and the provider discuss the patient's prescriptions.

"Through a CPA, I can order the prescription, order any ancillary drugs, order refills, and order labs," said Simonyan. "It really helps smooth the process and helps the patient have a point of contact for their treatment."

When people think of specialty pharmacy, they usually don't think about a clinical side, said Simonyan. "It leads to the question of how we are using a collaborative practice agreement," she said. "I'm very fortunate in that the physicians I work with heavily involve me in the treatment and decision-making process with the patient."

Working in an integrated health-system helps, too. Simonyan is able to mitigate issues when they happen because she can fill medications for patients, and she can pull up relevant information when it's needed.

Simonyan's role is hybrid. On days she works remotely, she is following up with patients via phone or telehealth meetings, managing other pharmacists on her team, and participating in the outcomes research projects within Vanderbilt Specialty Pharmacy.

A Vanderbilt team presented research at ASHP's 2023 summer meeting on implementing collaborative pharmacy practice within an integrated health-system specialty pharmacy, using their model to show how quality and efficiency of patient care improves and is favorably accepted by clinic staff. There is limited research that exists currently on collaborative pharmacy practice agreements within integrated health-system specialty pharmacy, even though a growing number of health systems are developing integrated specialty pharmacies that provide comprehensive specialty medication management.

"As more specialty drugs come out, there's more clinics touching and handling these drugs that really require a high-touch model," said Simonyan.

Jena Quinn, PharmD

Jena Quinn, PharmD

"There's this very hidden thing in the United States that no one is talking about that is called polypharmacy in pediatrics," said Jena Quinn, PharmD, owner of Perfecting Peds. Her team—all board-certified, residency-trained pediatric pharmacists—serve pediatric patients in long-term care, medical daycare, or home health.

"There are long-term care facilities all over the United States with kids getting subpar care," said Quinn. "This is the first time in U.S. history that a pediatric-trained pharmacist has come in and is doing medication reviews via a CPA."

Her team performs medication reviews, comprehensive clinical services, pharmacogenomics testing, and more.

Quinn wants to improve the quality of life for the children she's working with, many who are terminally ill, and subsequently better the lives of their caregivers. Her patients have not had comprehensive medication management done previously. Quinn said this should be the standard of care.

"These kids are at that threshold of five or more medications, and they almost always have medications errors or a lot of room for med optimization," said Quinn. "Many are on multiple meds, or are not on the right medication; they are mismanaged and experiencing lots of adverse effects," she said.

Quinn has been practicing in New Jersey under CPAs, and since starting Perfecting Peds, she's contracted with several New Jersey facilities. But Quinn knew that in order to grow her business and for anyone to take her seriously, she needed proof of concept with data.

In roughly 9 months of working under CPAs in these New Jersey facilities, Quinn and her team were able to build a cohort of 102 medically complex pediatric patients. With a total of 1,355 interventions, Quinn found a 44% reduction in hospital admissions or readmissions, 28 emergency department admissions or readmissions avoided as well as 61 clinic and urgent care visits, and an average reduction of 15% fewer medications per child.

For cost savings, they were able to save about $400 per month per child—$489,120 total annually.

> "This is the first time that a pediatric-trained pharmacist has come in and is doing medication reviews via a CPA."

The research is forthcoming in the *Journal of Pediatric Pharmacology and Therapeutics*.

Managed care organizations are taking note, too. According to Quinn, these are data she can take not only to insurance companies, but home care companies and other facilities.

Quinn has to be paid through the providers she's in contract with because the state of New Jersey does not recognize pharmacists as providers. But Quinn and her team recently became licensed in Minnesota, where they are recognized as providers and are credentialed with Minnesota Medicaid. They see patients via telehealth. Quinn has trained about 10 other pediatric pharmacists to work with her on her team.

"We got a headquarters in Minnesota with the Minnesota Epilepsy Group and are directly billing Medicaid patients," said Quinn. "As you can imagine, this patient population needs the most help, and we are finding so many opportunities there for med management." ■

Patients too trusting of online drug sellers

Sonya Collins

When patients look to the Internet for medications, their search could yield up to 45,000 online drug sellers. According to the National Association of Boards of Pharmacy (NABP), very few are legitimate; some 95% of so-called online pharmacies operate illegally. As patients are becoming increasingly comfortable with seeking medications online—a partial byproduct of the pandemic—it's crucial that they understand the risks involved.

Fewer than 15% of pharmacists discuss the risks of online pharmacies with their patients. In fact, more than half of pharmacists say they are not confident in their knowledge of illegal online pharmacies and the associated risks. However, pharmacists can play a critical role in protecting patients from this growing public health risk.

"One action step for pharmacists is to become knowledgeable about the scope of this issue," said John Hertig, PharmD, associate professor and department chair of pharmacy practice at Butler University College of Pharmacy and Health Sciences in Indianapolis. "The more knowledgeable our pharmacists are, the more willing they will be to engage in conversations about this with patients and family members at the point of care." Hertig has published research on illegal online pharmacies and is currently developing an educational module on the topic for pharmacists.

Here's what pharmacists need to know.

The problem

The ranks of online pharmacies that engage in some degree of illegal activity are growing daily. For the past 3 years, NABP has added an average of 200 online drug sellers to its Not Recommended List every week.

These online sellers' illicit activities include a variety of offenses whose impact on patients ranges from potentially benign to extremely hazardous. Online sellers may:

- Be unlicensed in both the state where they are operating and the state where they are sending prescriptions.
- Sell medications without a prescription.
- Sell substandard, falsified, or unapproved medications.

Risks to patients include over- or under-dosing, drug interactions, adverse events, and even death.

Nearly 90% of illegal online drug sellers dispense medications to patients without requiring a prescription. More than half of them sell controlled substances, according to NABP.

Substandard and falsified products are a particular patient safety concern as they may contain poisonous fillers. Some counterfeit drugs have been found to contain brick dust, heavy metals, rat poison, boric acid, and antifreeze.

WHO has long tracked the prevalence and consequences of substandard and falsified medical products in developing countries. The organization's most recent data show that 1 in 10 products in low- and middle-income countries fit this description.

Illegal online drug sellers are increasingly sending products to the United States.

"This is a patient safety problem here in the United States," Hertig said. "It's no longer just a developing or lower- and middle-income country issue."

Patients are susceptible

Hertig's research has found that patients choose online drug sellers for three key reasons: cost, convenience, and access. They may find better prices online. They can order and receive the drugs without leaving home.

"Access can be geographic access, where you actually can't get to a pharmacy," Hertig said, "or it could be lack of access because of stigma." Among those potentially stigmatizing drugs that patients might prefer to access online, Hertig cited PrEP and oral contraceptives.

But patients are overwhelmingly unaware of the potential risks. Some 7 in 10 Americans believe that drug sellers who appear high in Internet search results are trustworthy, according to Alliance for Safe Online Pharmacies Global Foundation's 2021 survey on American perceptions and use of online pharmacies. Four in 10 believe that any website offering medications has FDA or state approval to do so. ■

Pharmacists can help protect patients

Pharmacists can consider asking patients where they get their other medications. If patients are buying online, they should ask why. If the online source is potentially unsafe, pharmacists should offer alternative means for patients to get the medication.

Alert patients to common red flags that indicate a drug seller is not playing by the rules, including:

- Not requiring a prescription
- Advertising specific medications, such as sexual health drugs, on the site
- Discounts and buy-one-get-one (BOGO) deals
- Fraudulent use of seals or corporation logos
- Typos, misspellings, and other errors

Pharmacists can also point patients to websites that verify the legitimacy of online pharmacies, such as Safe. Pharmacy: https://safe.pharmacy/not-recommended-sites/ ■

Commercialization of COVID-19 vaccines raises concerns about access

Sonya Collins

Until this fall, COVID-19 vaccines have been free for everyone in the United States regardless of insurance, finances, or immigration status. But HHS has now phased out that program, and COVID-19 vaccines have transitioned to the commercial market. While CDC's Bridge Access Program makes free vaccines available to uninsured and underinsured adults through various pathways, critics have concerns about barriers to access.

"We had finally crossed the bridge of people in underserved communities being uneasy about getting the vaccine. Now we're in a place where they just can't find it," said Jacinda Abdul-Mutakabbir, PharmD, assistant professor of clinical pharmacy at the San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences at the University of California. "Vaccine hesitancy, we could work on that. But no access? That's a major limiting factor."

COVID-19 vaccines still free... for most

Now that the COVID-19 public health emergency has ended, COVID-19 vaccines are no longer free for everyone. However, they are still free for most people. Medicare, Medicaid, and ACA-compliant commercial health insurance will cover the vaccine for adults. Children will continue to receive the vaccine free of charge through commercial insurance, the Vaccines for Children Program, and the Children's Health Insurance Program, according to HHS' Administration for Strategic Preparedness and Response.

The estimated 25 to 30 million U.S. adults who are uninsured, or those whose health insurance does not cover the vaccine, such as pre-ACA grandfathered plans and short-term limited-duration insurance plans, can get free COVID-19 vaccines at federally qualified health centers; state, local, tribal, or territorial health departments; and pharmacies participating in CDC's Bridge Access Program, which include CVS, Walgreens, and eTrueNorth pharmacies. Uninsured adults who get free vaccines might be charged an administration fee.

Foreseeable gaps in access

The Bridge Access Program leaves it up to participating pharmacies to verify patients' eligibility to receive a free COVID-19 vaccine. The onus is also on these pharmacies to make potential beneficiaries aware of the program. Among the program participation requirements outlined by HHS is to conduct outreach to underserved communities and others who may be eligible. Underserved patients' access to vaccines depends on pharmacies' capacity to create widespread awareness of the program.

It's clear, said Abdul-Mutakabbir, that so far, uninsured and underinsured patients do not know where they can get updated COVID-19 vaccines.

"When we do vaccine clinics, we have people coming from 30, 40, or even 50 miles away because they don't know where else they can go to receive the vaccines," she said. These community-based pop-up clinics, supplied with vaccines provided by the government, will now become fewer and further between, she added.

This underscores concerns that when under-resourced patients are no longer able to get COVID-19 vaccines where they were accustomed to getting them in the past, such as churches and community centers, they may stop getting them altogether.

Many people, if they are motivated to do so, may have to travel much further than 50 miles to get COVID-19 vaccines for themselves and their families. Some 59 million Americans live in pharmacy deserts. Others may live in rural areas where the lone independent pharmacy is not contracted with CDC's Bridge program.

Many of those whose only means of obtaining an updated COVID-19 vaccine is through cash-pay won't be able to afford this option.

"It's just the unfortunate circumstance that we are in, and it's one where we are going to continue to see this gap that is just going to keep widening," Abdul-Mutakabbir said. "In my opinion, we're taking three steps back in terms of vaccine access."

The Biden administration appealed to the manufacturers to price the vaccines reasonably and affordably, but it has not offered any incentive to do so. According to *Health Affairs*, the government invested nearly $32 billion in mRNA vaccine research, development, and procurement, much of which went to buying the vaccine from the drugmakers at $15.25 to $30.48 per dose, depending on the manufacturer and the iteration. The drugmakers have set the commercial prices at up to more than four times those original prices at $110 to $130 per dose.

"We are a revenue-based health care system," Abdul-Mutakabbir said. "Our best hope is if the companies themselves would take some responsibility for addressing these gaps because they are the ones who determine the price." ■

Pharmacists can provide care for psychiatric conditions within the prison system

Ariel L. Clark, PharmD

Mental health and psychiatric conditions affect millions every year. Within the prison system, inmates' mental health conditions are compounded by limited providers, lack of access, and complexity of care. Coupled with bureaucratic and political hardships as well as the COVID-19 pandemic, which was a catalyst for increased mental health crises, providing care for incarcerated patients continues to pose a challenge.

Researchers of a study published May 4, 2023, in *JAPhA* investigated how pharmacists could fill gaps in care with a new inpatient psychiatric pharmacist service. The study found that integration of a pharmacist in the Federal Correction Center (FCC) at Butner Medical Center in North Carolina inpatient psychiatric program improved inmate treatment acceptance and drug monitoring, and reduced overall cost related to the treatment of psychiatric conditions.

At the FCC at Butner Medical Center in North Carolina, over 60% of inmates have a mental health condition—more than double the prevalence for those who are not incarcerated.

Drawing on the successful collaboration within primary care for patients with chronic conditions like diabetes, this investigation of the Butner FCC pharmacist service relies on CPAs to manage treatment for patients with conditions such as schizophrenia, bipolar disorder, ADHD, and more.

Pharmacist impact on treatment

The study investigated FCC Butner's nearly 4,000 psychiatry visits for 241 inmates in the center between January 2020 and March 2023. The inpatient pharmacist directly provided 576 of the visits and services for 892 additional visits. Over the course of the study, the pharmacist followed 125 patients directly and interventions included medication reviews, adjustments, and extensive education provided directly to patients.

At the start of the new program, 25 inmates admitted to the psychiatric center were not taking any medications for their condition. In these cases, the inpatient pharmacist held and directed antipsychotic psychoeducation meetings with those who were interested to discuss patient questions and dispel misconceptions about treatment with antipsychotics.

Inmates were encouraged to submit questions prior to the meetings, and they were able to not only get their questions answered, but were also able to hear directly from inmates who started treatment successfully. At the conclusion of the study, 15 of those who originally refused treatment accepted and began medication therapy for their conditions.

Pharmacist impact on monitoring

Many antipsychotic medications require monitoring due to their narrow therapeutic index. Clozapine, for example, causes severe neutropenia and requires monitoring for the duration of its use. Many other medications require monitoring for weight gain, increased cholesterol, and involuntary movements, among others.

As a result of the FDA REMS program, providers monitored clozapine in 100% of patients who receive it at FCC Butner. But a review for metabolic and movement changes were lacking in 19% and 100% of cases, respectively. The study found that when the psychiatric pharmacist came onboard, they were able to improve monitoring according to national and Bureau of Prisons guidelines in 100% of cases.

Takeaways

Several previous studies have shown that using pharmacists in collaboration with prescribers can decrease costs. This study found similar results and estimated that putting in place an inpatient psychiatric pharmacist resulted in over $100K in cost savings.

Care for patients who are incarcerated with concomitant psychiatric and mental health conditions is limited in the same ways that it is for the general population. This study showed that the use of a pharmacist to close this gap in care can improve adoption of treatment, patient monitoring and outcomes, and can decrease cost for inmate care.

More studies that emulate this investigation are needed to see the full extent of improvement in outcomes and other measures as a result of pharmacist interventions within the Bureau of Prisons. ■

Correct Rx: Based on the practice of clinical pharmacy

Correct Rx, a 20-year-old provider of correctional and clinical pharmacy services, received a Pinnacle Award this year from the APhA Foundation. Clinical pharmacists with CorrectRx work directly with health care providers and patients in a unique clinical pharmacy delivery model.

They provide services to over 200,000 incarcerated individuals in over 400 correctional and juvenile facilities. Correct Rx is based in Maryland, but pharmacists are licensed in 49 states and currently deliver correctional pharmacy services in 35 states and Washington, D.C.

Collaborative practice now allowed in all 50 states

Lauren Howell, PharmD

On August 17, 2023, Delaware became the 50th state to pass legislation allowing pharmacists and prescribers to enter into collaborative practice agreements (CPAs) in which one or more pharmacists can provide patient care and drug therapy management services that are not otherwise permitted to be performed by a pharmacist. With the signing of this bill, every state now recognizes CPAs between pharmacists and prescribers.

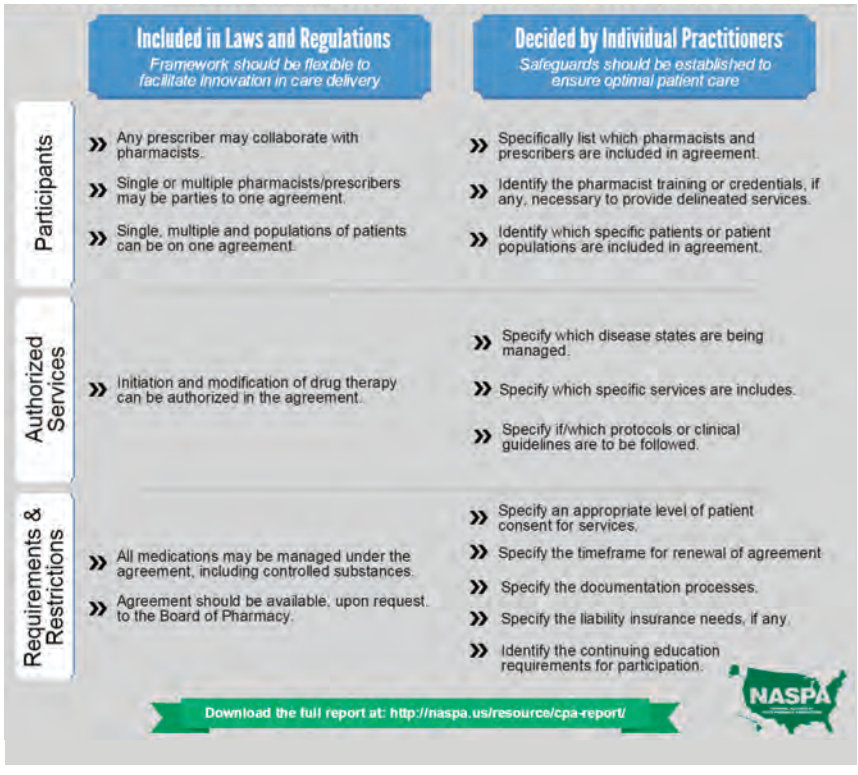
CPAs allow prescribers and pharmacists to establish a formal relationship in which a prescriber can delegate tasks to a pharmacist under negotiated conditions. The prescriber is most often a physician, although a growing number of states are allowing for CPAs between pharmacists and other prescribers such as nurse practitioners. These tasks may include patient care delivery services, such as chronic care management, refill authorizations, initiation of therapy, and formulary management. The agreements serve as a way to allow patients more access to care, increase the efficiency of patient care, and use a pharmacist's medication expertise to complement the services and knowledge that other members of the health care team provide.

Legislative and regulatory authority

In July 2015, the Collaborative Practice Workgroup, convened by NASPA and made up of representatives from NACDS, AACP, APhA, NCPA, AMCP, NABP, ASHP, ACPE, and ACCP, as well as state pharmacy associations, met to formalize recommendations for the key elements of legislative and regulatory authority. The group worked to recommend which elements of collaborative practice authority should be codified in state law or regulations and which elements are more appropriately defined by the parties who voluntarily enter into a CPA at the practice level.

This workgroup made recommendations concerning CPA participants, authorized services, and requirements and restrictions. The specific recommendations that the workgroup made can be seen in the infographic below.

Although these recommendations were made over 8 years ago, the need for standardization around these topics still exists today in order for the widespread adoption and implementation of these agreements to occur.



Differences among states

While all 50 states now recognize CPAs between pharmacists and prescribers, there are many differences between what is permitted in each state.

Some of the differences in CPAs between states include requirements of continuing education, liability insurance, and documentation of services. Additionally, some states require patient involvement in the agreement. A patient may have to sign that they agree to receive services as part of the CPA, or they may be able to opt out of these arrangements. Some states have chosen to mandate that the agreements be approved by a state agency or have defined a length of time that the agreements may be valid. Adding to the confusion, some states have chosen not to address these issues at all in legislation, leaving prescribers and pharmacists to figure it out for themselves.

This lack of standardization makes implementation and scaling of these authorities difficult. It also creates complications for national organizations that want to put these authorities into practice, as they have to navigate the legality of each state individually instead of on an organizational level.

While the recognition of CPAs in all states is a huge win for pharmacy, it is imperative that national standardization occurs so that pharmacists, as drug experts, can practice at the top of their license to improve health outcomes for patients. ■

One size does not fit all: Providing access to patients with disabilities

Mickie Cathers

About one in four adults live with a disability, according to CDC. Disabilities—whether of the body or mind, lifelong or temporary—are a universal experience that affects nearly everyone at some point in their lives.

Disability imposes restrictions on participation and limitations on activities, including access to health care.

"As pharmacists, we have an incredible impact for helping patients with these challenges," said Steve Erickson, PharmD, associate professor of clinical pharmacy at the University of Michigan, during a session at the 2023 APhA Annual Meeting & Exposition in Phoenix. Pharmacists are in a unique position to deliver and improve equal access for patients with disabilities and support those patients as they navigate the health care landscape.

Having a disability that is associated with chronic conditions and polypharmacy is also a common problem. Patients with disabilities often have a complex medication regimen similar to those of the nursing home population, with a high prevalence of drug interactions."People with developmental disability have significantly higher hospitalization due to adverse medication events in comparison to the general population," said Erickson. Patients with heart failure or atherosclerotic CVD and intellectual disability are significantly less likely to receive guideline-based treatments such as ACE inhibitors—especially those with Down Syndrome—and beta-blockers.

Accessible health care

There are two models of disability: medical and social. The medical model views disability as a problem that exists in a person's body and requires medical treatment. This leads the person with a disability to feel excluded, undervalued, pressured to fit in, and patronized. The social model of disability distinguishes between impairment and disability, identifying the latter as a disadvantage that stems from a lack of fit between a body and its social environment. Disability results from the interaction between individuals with a condition and personal and environmental factors, including negative attitudes, inaccessible transportation and public buildings, and limited social support. This this further comttpounded by other social determinants of health such as race/ethnicity, age, language, sex or gender, poverty, and education level.

"It's the environment that makes the impairment disabling," said Erickson. "Think of your practice site. Is there access to the pharmacy with handicap parking, and clear pathways and signage? How loud or bright are the sounds and lightingw in the pharmacy area/waiting room/exam room environment? What is the length of time to access services, what is the wait time to have a prescription filled, is there enough time during consultations?"

Cultural competence

To be healthy, everyone—those with and without disabilities—needs the tools and knowledge to promote wellness along with access to appropriate, integrated, culturally sensitive, and respectful health care.

"Become aware of your bias and society's view of this population," said Erickson. Steps for becoming culturally competent include valuing diversity and acceptance of differences; embracing self-awareness and consciousness of the impact of culture, beliefs, and attitudes when interacting with patients; and building knowledge of a patient's culture.

"Know the people you serve," Erickson said. "Know their needs. Reach out and learn from them. Be sensitive and accommodating to the needs of individuals and that person's cultural perception of disability. Asking the right questions and listening to patients describe their experiences is a first, good step." ■

Disablity etiquette: Interaction

Mobility impairment	Don't touch or push a wheelchair; physically bring yourself down to the patient's level.
Visually impaired	Identify yourself; do not speak to or touch a service animal that is working.
Deaf or hard of hearing	Speak directly to the person. Do not assume the person reads lips; do not chew gum or wear sunglasses. If masking, use a clear mask.
Respiratory or multiple chemical sensitivity disorder	Refrain from wearing perfumes and maintain good ventilation.
Intellectual/Developmental disabilities	Speak directly with the patient; present one concept at a time; have patience; use shared decision making; listen to the caregiver.
In general	Avoid condescending tones or an infantilizing manner. Be mindful of speech quality, including tone, loudness, and speed.

Source: APhA2023

Community resources

- The Arc: Policy and advocacy for persons with IDD
  https://thearc.org/
- Centers for Independent Living
  www.ilru.org/home
- Autistic Self Advocacy Network
  https://autisticadvocacy.org/
- American Council of the Blind
  www.acb.org/
- Ask your patients!

Oral care, pain and inflammation, and other

Tooth hypersensitivity affects 10–30% of the population, and worldwide, 30% have experienced migraine and 50% of the population suffered from headache in the past year. Patients will be looking for advice and assistance with their decision-making process as they search for relief of their pain and discomfort.

Oral care

Cold sore relief

Abreva 1

Dry mouth relief

Biotene 1

Oral pain relief

Orajel 1
Tylenol 2

Pain and inflammation

Back pain relief

Advil 1
Aleve 1
Tylenol 2

Rapid headache relief

Excedrin 1
Tylenol 2
Advil 3

Rapid migraine relief

Excedrin 1

Other

Incontinence products

Depend 1
Poise 2

Shampoo for severe dandruff

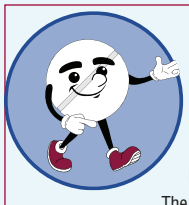
Head & Shoulders 1
Selsun Blue 2
Nizoral 3

Sleeping aid

Unisom 1
Benadryl 2
Vicks ZzzQuil 3

Smoking cessation

Nicorette 1
NicoDerm 2



Self-care survey redux

This section of *Pharmacy Today*'s Self-Care Product Survey is reprinted from the full survey results published in the August 2023 issue of the magazine and available online at pharmacytoday.org.

The current survey was conducted by BrandSpark/Newsweek International using scientifically valid methodology, and lists those nonprescription products most often recommended by pharmacists in the United States to consumers.

The winners were selected based on a survey of 1,716 pharmacists practicing in the United States who gave their unaided write-in opinions on which brands they'd recommend to patients in 86 categories. The highest share of citations as most trusted in the category determined the winner. If the margin of citation share between the leading brands did not exceed the estimate of sampling error at 90% statistical confidence, a tie was declared.

Please also see APhA's *Handbook of Nonprescription Drugs*, the definitive source of professional information about OTC products. The *Handbook* is available online at PharmacyLibrary.com.

Court limits patient responsibility to detect pharmacy error

David B. Brushwood, BSPharm, JD

A "wrong-drug" error in order processing is the most frequent type of pharmacy malpractice lawsuit. In some circumstances, a patient's failure to recognize a wrong-drug error can be a defense to a pharmacy malpractice case based on what is legally referred to as "contributory negligence."

The patient's responsibility for detecting a pharmacy error is generally considered to be a question of fact for a jury to decide and not a question of law for a judge to determine. However, a federal court in Alabama recently refused to dismiss a pharmacy malpractice case in which the defendant pharmacy asserted the patient's contributory negligence as a defense.

The court observed that the legal standard to support dismissal of this case as a matter of law "is not whether [the patient] *should have* appreciated the risk but whether he *consciously* appreciated the risk."

Background

The patient had received both carvedilol and hydralazine from the defendant pharmacy for many years. His lawsuit alleged that on one occasion, a refill of his carvedilol was incorrectly processed with hydralazine. He checked the label and saw that the information on the label was correct. He did not contact the pharmacy because he "trusted [the pharmacy] to give him the correct pills and he felt no need to verify what he had been given."

He explained that "when he saw the pill had changed shape and color, he thought it was another generic kind of pill because they change colors, they change shapes." He did not contact the pharmacy to verify that the contents of his medication vial were correct.

The patient alleged that he "felt dizzy and lightheaded, his chest began hurting, his heart was beating fast, and his blood pressure was above 200." He was transported to the hospital, and he was treated for the effects of a hydralazine overdose. His lawsuit alleged that the pharmacy had negligently placed 50 mg hydralazine tablets in a vial labeled as 6.25 mg carvedilol.

The defendant pharmacy moved for dismissal of the case, contending that "because [the patient] knew there were risks associated with taking these medications incorrectly, he was contributorily negligent when he took the pills without trying to verify the medication was correct."

Rationale

The court first noted that the defense of contributory negligence will support dismissal of a malpractice lawsuit only if "there is no genuine issue of material fact as to any element of that defense." To establish contributory negligence as a matter of law, a defendant pharmacy is required to establish that the patient "(1) put himself in danger's way and (2) had a conscious appreciation of the danger at the moment the incident occurred."

The court noted that the pharmacy was essentially arguing that the patient "*should have* doubted the pill was carvedilol because he realized the pill looked different, even though he had just taken it out of a bottle labeled carvedilol; therefore, he *should have* known the pill was hydralazine instead of carvedilol—or at least he should have taken some action to confirm the pill was carvedilol." The court observed that the legal standard to support dismissal of this case as a matter of law "is not whether [the patient] *should have* appreciated the risk but whether he *consciously* appreciated the risk."

The court was unaware of any legal authority supporting a conclusion that, as a matter of law, [the patient] "having picked up a prescription he previously filled many times at [the pharmacy] was required to affirmatively question the pharmacy about why the appearance of his pills had changed."

The pharmacy's motion to dismiss was denied.

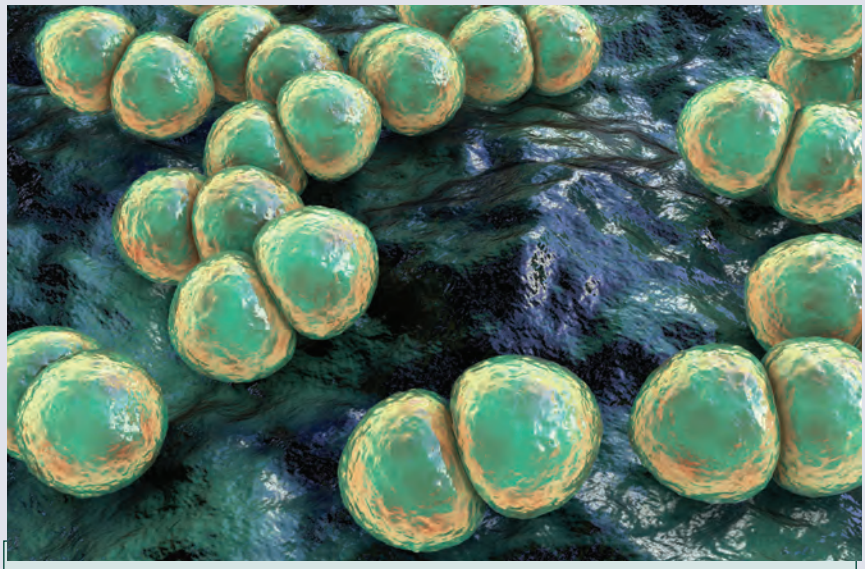
Takeaways

Pharmacists cannot rely on patients to detect and rectify dispensing errors. Order processing accuracy is a pharmacy responsibility.

Patients should be encouraged to ask their pharmacist if they have any questions about their medications, and all questions should be taken seriously.

If the appearance of a dosage form changes when a continuing supply is provided to a patient, such as a refill with a different generic product, then the patient should be informed of the change. ■

Inpatient*Insights*



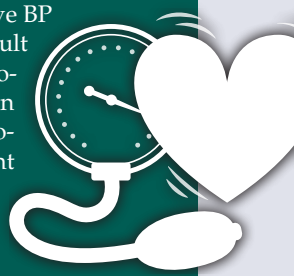
Researchers evaluate antibiotic effectiveness for cellulitis

Although most cases of cellulitis are uncomplicated and can be resolved in the community setting, the number of patients hospitalized for cellulitis has increased in recent years. The length and route of antimicrobials needed to resolve the infection are unclear, with approximately 20% of patients with cellulitis prescribed repeat courses of antimicrobials when it is likely that many of the patients have slowly resolving symptoms and additional treatment is unnecessary. Researchers from the University of Bristol and the Bristol Royal Infirmary (UK) used data from a randomized clinical trial of clindamycin as adjunctive therapy in cellulitis to illustrate the evolution of local parameters (pain, swelling, local erythema, and warmth) and the resolution of biomarkers over time.

Data from 247 individuals with mild to moderate unilateral lower limb cellulitis were used to examine antibiotic response dynamics. Results of the study, published in the October 2023 issue of *Open Forum Infectious Diseases*, indicated a local improvement in swelling, warmth, erythema, and pain by day 5 compared with baseline, though some individuals still had evidence of local inflammation at 10 days. Most biomarkers demonstrated a return to normal by day 3, although the initial fall in albumin only returned to baseline by day 10.

The authors suggest that clinicians can use these data to reassure themselves and their patients that ongoing local symptoms and signs after completion of antibiotic treatment do not indicate treatment failure or warrant extension of the initial antibiotic treatment or a change in antibiotic class or mode of administration. ■

Does orthostatic or standing hypotension change the effectiveness of intensive BP treatment?



Concerns remain about the benefits of intensive BP treatment for adult patients with orthostatic hypotension or standing hypotension. In a recent study in *JAMA*, published online on October 17, 2023, a multinational group of researchers sought to determine the effect of a lower BP treatment goal or active therapy versus a standard BP treatment goal or placebo on CVD or all-cause mortality in patients with orthostatic or standing hypotension.

The study involved an individual data meta-analysis of more than 29,000 participants in nine hypertension trials based on a systematic review of MEDLINE, EMBASE, and CENTRAL databases through May 13, 2022. The researchers found that more intensive BP treatment lowered risk of CVD or all-cause mortality regardless of whether participants had orthostatic hypotension. Effects did not differ by the presence or absence of standing hypotension.

The authors indicate asymptomatic orthostatic hypotension or standing hypotension among adults with hypertension should not be a deterrent to more intensive hypertension treatment. ■

Is rosuvastatin or atorvastatin more effective in adults with CVD?

Reduction of LDL cholesterol levels is commonly recommended for patients with coronary artery disease to lower the risk of atherosclerotic cardiovascular events.

A recent study, published in the *BMJ* on October 18, 2023, compared the long-term efficacy and safety of the two most common statins used in this patient population, rosuvastatin and atorvastatin. The randomized, open label, multicenter trial was conducted in 12 hospitals in South Korea from September 2016 to November 2019.

More than 4,400 adults with coronary artery disease were assigned to receive either rosuvastatin (n = 2,204) or atorvastatin (n = 2,196) using 2×2 factorial randomization. Mean daily dose of study drugs was 17.1 mg in the rosuvastatin group and 36.0 mg in the atorvastatin group at 3 years.

The primary outcome (a 3-year composite of all-cause death, myocardial infarction, stroke, or any coronary revascularization) occurred in 189 patients in the rosuvastatin group and 178 patients in the atorvastatin group and the mean LDL cholesterol level during treatment was 1.8 mmol/L in the rosuvastatin group and 1.9 mmol/L in the atorvastatin group.

More patients in the rosuvastatin group developed new onset diabetes and underwent cataract surgery than in the atorvastatin group. Other safety endpoints did not differ between the two groups.

The authors note that because only Asian patients were included in this trial, the results may not be applicable to all populations.

In addition, the 3-year study may have been relatively too short to discover longer term effects of the two statin types. They suggest that these findings should be interpreted with caution and that further dedicated investigation with longer follow-up is warranted. ■

Do cefepime and piperacillin-tazobactam increase the risk of acute kidney disease or neurological dysfunction?

Patients hospitalized with acute infections are often given cefepime and piperacillin-tazobactam to treat the infection. However, it has been suggested that piperacillin-tazobactam may cause acute kidney injury and that cefepime may cause neurological dysfunction. Researchers in the Vanderbilt Center for Learning Healthcare and the Pragmatic Critical Care Research Group conducted a randomized clinical trial (ACORN) to determine whether the choice between cefepime and piperacillin-tazobactam affects the risks of acute kidney injury or neurological dysfunction.

More than 2,500 adult patients for whom a clinician had initiated antipseudomonal antibiotics within 12 hours of presentation to the hospital were randomized in a 1:1 ratio to receive either cefepime (as an I.V. push over 5 minutes) or piperacillin-tazobactam (as an initial bolus and extended infusions over 4 hours for subsequent doses). The primary outcome of the study was the highest stage of acute kidney injury or death by day 14, measured on a five-level scale ranging from no acute kidney injury to death.

The study, published on October 14, 2023, in *JAMA*, showed that the highest stage of acute kidney injury or death was not significantly different between patients in the cefepime group and those in the piperacillin-tazobactam group, and the incidence of major adverse kidney events at day 14 did not differ between patients in the two groups. However, patients in the cefepime group experienced fewer days alive and free of delirium and coma within 14 days than those in the piperacillin-tazobactam group. ■

Hospital's process improvement harmonizes I.V. infusion medications across multiple systems

Corey Diamond, PharmD

Bringing together an electronic health record (EHR) system, an infusion smart pump library, and an I.V. infusion policy to share consistent information can be a challenge for any large hospital system. When the standard concentration policy, pump library, and EHR are out of sync, it creates confusion for pharmacy and nursing staff. As discrepancies between these systems are bound to occur, clinicians are looking for guidance.

A new process improvement method published in Supplement 3 (September 1, 2023) of the *American Journal of Health-Systems Pharmacy* may provide valuable insight into how EHRs, I.V. infusion policies, and infusion smart pump libraries may be proactively harmonized to avoid harmful medication errors.

Christensen and colleagues conducted a process improvement project at the five hospitals, including a flagship level I trauma center with 546 beds, of the University of Utah health center. The system delivers over 1 million infusions annually.

The health system already had processes in place to update the infusion policy, the pump library, and the EHR; there was, however, a need for a more proactive and formalized process to ensure medication listings are harmonized between them.

"Standardizing these resources can help reduce confusion, improve efficiency in both pharmacy operations and nursing workflow, and improve patient safety," said the researchers.

Process improvement methodology

The project's goal was to evaluate the differences between these three sources and to create a new process within existing frameworks to maintain uniformity.

This involved proactively evaluating and synchronizing I.V. infusion guidance data across their health system's I.V. administration policy, infusion smart pump library, and EHR.

The researchers amended their institution's processes so that when a medication-related change was requested in one of the three sources—the I.V. infusion policy, pump library, or EHR—it was shunted through both the institution's drug information system and pharmacy informatics system so that any change to one source would force an update to the remaining two sources.

In other words, prior to releasing changes to the EHR, pump library, or policy, the new method allowed the institution's pharmacy informatics team to perform a prospective double-check to ensure that all three resources were concordant with one another at the time a medication change was requested.

Data evaluation

The researchers evaluated a total of 187 entries consisting of 84 I.V. infusion medications. They identified a need for 48 policy updates, with the most common themes being updating concentration units and adding medications to the policy.

There were also a few instances of concentrations being available in the EHR but not included in the infusion policy.

As an example, the researchers point to dobutamine, which had its concentration listed in "µg/mL" in the EHR, but as "mg/ml" in the policy.

Recommendations

The investigators recommended 30 updates to the pump library, primarily adding dosing concentration units for nursing staff.

In a few instances, medications needed to be added or the concentration updated in the pump library. For example, a concentration of isoproterenol was programmed in the library but was not available in the EHR or the policy. They recommended removing the pump programming option.

When multiple resources disagreed, the researchers chose to update the EHR. For example, there was no hard volume limit in the EHR build for bivalirudin, which made it possible to change the base volume of the infusion, thereby changing the concentration.

"Standardizing these resources can help reduce confusion, improve efficiency in both pharmacy operations and nursing workflow, and improve patient safety."

Next steps

Next steps for this study include stakeholder review of the appropriateness-feasibility of the 82 recommendations, along with a review of the infusions that were not evaluated in this study, including pediatric snd neonatal, intermittent, PCA/epidural, and continuous/extended antibiotic infusions as well as any infusions in procedural areas. ■

Procalcitonin-guided antibiotic protocol could reduce unnecessary prescriptions

Emily Albers, PharmD

COVID-19 illness with bacterial coinfection can be difficult to identify because coronavirus presents similarly to bacterial infection. Even when properly identified, coinfection is uncommon. Coinfection only occurs in about 8% of patients with COVID-19, but 60% to 80% of patients are prescribed antibiotics as a contingency plan.

Unnecessary, empiric antibiotic administration can lead to antimicrobial resistance and superinfection, affecting health systems' antibiotic armory in the long run.

To combat high antibiotic prescription rates, researchers have looked toward biological markers as a source of stewardship. One study, published in the April 2023 edition of the *CHEST Journal*, investigated the use of a procalcitonin-guided antibiotic protocol and the subsequent impact it had on antibiotic administration.

The study found that when hospitals put in place a procalcitonin (PCT)-guided antibiotic protocol, antibiotic prescription rates in hospitalized patients with COVID-19 were reduced, without major safety concerns.

Study methods

The multicenter cohort study was based out of the Netherlands in collaboration with the COVIDPredict study group. COVIDPredict is a multicenter initiative in the Netherlands, which collects data on patients hospitalized with COVID-19. While previously there have been retrospective assessments validating the use of PCT levels, this is the first study prospectively evaluating the implementation of a PCT-guided protocol.

Patients were enrolled from October 2020 to July 2021 into three patient groups. The study group included patients from one set of clinics on antibiotics with PCT-guided protocol. The second group retrospectively analyzed patients from the same clinics treated without PCT guidance. The third group, the control, consisted of patients from three additional COVIDPredict hospitals without PCT guidance.

All study patients were admitted to a hospital, were 18 years or older, and diagnosed with COVID-19 via positive sample test. PCT levels were measured within 24 hours of admission. PCT levels are normally lower than 0.1 µg/L in healthy adults, and only raised in bacterial infections, not viral. In the PCT-guided study group, the protocol used by prescribers was that if PCT levels were lower than 0.25 µg/L, antibiotics were discouraged. If PCT levels were 0.25 to 0.5 µg/L, antibiotics could be considered. If PCT levels were greater than 0.5 µg/L, antibiotics were recommended. A prescriber could override these decisions with rationale.

The primary outcome was the proportion of antibiotic prescriptions during the first 7 days of admission. Secondary outcomes included proportion of antibiotic prescriptions during the total stay, length of hospital stay, admission to ICU, mechanical ventilation, noninvasive ventilation, 30-day all-cause mortality, 90-day all-cause mortality, and readmission within 30 days.

> The study's high rate of adherence at multiple sites showed that using a PCT-guided antibiotic protocol is feasible.

Results

In the first 7 days of admission, 26.8% of PCT-guided protocol patients were prescribed antibiotics. In the non-PCT group, 43.9% of patients were prescribed antibiotics, and 44.7% of the control group were prescribed antibiotics. During their total admission timeframe, 35.2% of patients in the PCT group, 43.9% of the non-PCT group, and 54.5% of the control group were prescribed antibiotics.

There were no significant differences in the secondary outcomes other than readmission within 30 days, which had a higher rate for the PCT-guided group but were mainly noninfectious.

The actual prevalence of bacterial infection in patients with PCT levels above 0.50 µg/L was 10.6%, but the prescription rate in this group was still 26.8%. Prescribers adhered to the protocol 94% of the time in patients with PCT lower than 0.25 µg/L, and 100% in patients with PCT greater than 0.50 µg/L.

Impact

This multicenter cohort study shows that a PCT-guided antibiotic protocol can reduce the number of patients with COVID-19 who were treated with antibiotics in the first 7 days of admission. Patients managed with the PCT-guided protocol had fewer antibiotic prescriptions in the first 7 days of admission and throughout their total hospitalization.

The study's high rate of adherence at multiple sites showed that using a PCT-guided antibiotic protocol is feasible. Even so, antibiotic prescriptions still outnumbered true infections. Follow-up studies should consider using a higher PCT level cutoff. Pharmacists that receive these orders must be diligent antimicrobial stewards.

This study did not compare PCT-guided protocol to standard care. The Infectious Diseases Society of America still describes PCT as an unpredictable biomarker to identify coinfection. A PCT-guided protocol may be used safely in patients with COVID-19 to reduce risk of resistance and superinfection, but may not be superior to clinical judgment and current practice. ■

Pharmacist-led clinic reduces barriers to care in treating hepatitis C virus

Elizabeth Briand

In the United States, approximately 2.4 million people are living with the hepatitis C virus (HCV), including more than 65,000 in Washington state. There, a pharmacist-led clinic is reducing barriers to care and bringing treatment to patients in need in Seattle and surrounding communities.

"The idea came about several years ago as a project to reduce hepatitis C in our community, specifically among people who use injection drugs," said Kathleen Pierce, PharmD, pharmacy manager for Kelley-Ross Capitol Hill Pharmacy.

Pierce noted that the WHO has set a goal of eliminating HCV by the year 2030. "The cure is relatively easy to achieve with the direct acting antiviral hep C medications," she said.

Treating and curing people who inject drugs is key to controlling the disease, as injection drug use is a primary method of transmission for HCV.

"There are many barriers to care for people who use drugs," said Pierce. "Increasing low-barrier access to care is absolutely vital to getting these folks the health care they need and deserve. Pharmacists can fill this role and be a part of the solution to eliminate this infectious disease."

"The idea was to model the hep[atitis] C clinic on our already existing and very successful pharmacist-run HIV PrEP clinic," said Pierce. "Dr. Tsui applied for funding for the study through the National Institute on Drug Abuse and we were off and running."

Although the study has ended, the clinic continues with the help of other committed collaborators.

Working with Tsui, whom Pierce described as a "huge advocate for pharmacists," allowed the pharmacy team to expand connections to other physicians and care team members who have fleshed out staffing. In addition, the Hepatitis Education Project, a local medical case management and syringe service program, has provided invaluable assistance. Additionally, working with a local supportive housing group has helped the clinic connect with individuals who need help and has provided space in which to see patients.

"This program helps us meet folks where they are already going to be—at a syringe service program or a methadone clinic or their own apartment building—and makes it a one-stop shop," said Pierce.

"Increasing low-barrier access to care is absolutely vital to getting these folks the health care they need and deserve."

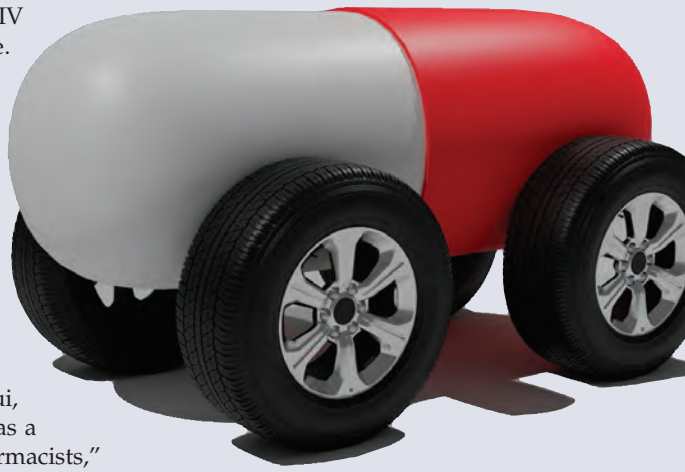
Reaching those in need

The HCV clinic came about after Judith Tsui, MD, an addiction medical specialist at Seattle's Harborview Medical Center Adult Medicine Clinic, approached the clinical team at Kelley-Ross to collaborate on a study assessing the success of community pharmacists in treating hepatitis C in people who inject drugs.

Pharmacists make care accessible

Pharmacists have been the not-so-secret weapon in the sustainability and effectiveness of the clinic.

"The pharmacist can provide all sources of care—the medical assessment, the lab draw, even delivering medication—so the patient doesn't need to navigate complex health care systems," said Pierce.



"Folks who use drugs often have a lot of competing priorities. When people have to figure out where they will sleep, how they will eat, and how they will avoid going into withdrawal, going to the doctor to get their hep C treated becomes a very low priority. [With this program], we are working on the hardest-to-reach people who tend to be the people who can spread the infection the most."

For the pharmacists who have participated in the program, the experience has been a meaningful one. "I think it demonstrates the unique role pharmacists can fill in providing multiple aspects of medical care in one step," said Pierce. And on an individual level, "not only are we able to serve our community in a much-needed way, but we are able to work at the very top of our license and make medical care easy to access for those who need it most." ■

A minute with ...

Ha Phan, PharmD, CDCES, BCACP, clinical assistant professor, University of Mississippi School of Pharmacy, and ambulatory care pharmacist, Pediatric Endocrinology Clinic and Pediatric Weight Management, Jackson, MS

Member since 2013

"Membership in APhA since my P1 year of pharmacy school has led to opportunities in leadership, service, and mentorship. My most memorable experience as a student pharmacist would be when I was able to travel to Croatia through the IPSF exchange program and work in a community pharmacy in Zagreb for 2 weeks. As a pharmacist, the opportunity to be a student chapter advisor has excited me to collaborate with student pharmacists and continue to serve our Jackson, MS, community and our patients through APhA–ASP."

How has APhA helped you establish meaningful connections?

Through working with student pharmacists and other pharmacists and my experiences with APhA, conferences are more exciting to attend. I'm able to catch up with new and old friends and meet new pharmacists who may have similar interests as I move through my career.

How does APhA help you thrive in your everyday practice?

Professional development activities throughout the year remind me of my "why" and refresh my drive for moving the profession forward.

What excites you about the profession of pharmacy?

The successes within other states and the experience that I gather while observing or learning from other pharmacists motivates me to cultivate similar experiences for both my students and the patients I serve.

Can you share a meaningful story about a time you interacted with a patient? Perhaps a time you felt like you really made a difference for them?

Our patients in Mississippi come from many different demographics; we have areas of the state that are truly pharmacy deserts, and some patients who may have a pharmacy nearby may not have transportation to access their medications. I saw a patient who was referred to me for diabetes management due to labile blood glucose. The local fire department down the road from his home provided emergency glucagon and, as the patient recalls, "sugar" because he was so out of it. He was on Novolin 70/30 due to cost. I was able to work with him to reduce midday and nighttime lows. I helped him with qualifying for patient assistance, and he was transitioned to a basal/bolus regimen with a GLP-1.

The more I talked to him, I started to realize that his meal choices were not always something that he could control, but were rather what he could get. Often, his lows were treated by the foods he had on hand and were not always what we would counsel patients to eat. We worked so hard together to get his A1C as close as we could to his appropriate goal of 7%; however, we continued to have variability based on the food he could access on a week-to-week basis.

There was a program that existed in Jackson for patients with food insecurities where I picked up food for an older patient. One day, this patient didn't have room in her refrigerator for some of the food I was dropping off to her, and she told me to give it to someone in need. I drove out to my patient's house and dropped off a 10-pound turkey. His day was made, and so was mine. I could see the comfort of knowing that he may not have to worry about food for a few days, and it also happened to be his birthday! Moments like these—when pharmacists are in the position to impact patients beyond medications, when we just take the time to get to know our patients and their barriers—reminds me of the value of our profession. ■

Get involved in APhA

Public Health SIG

The primary purpose of the APhA–APPM Public Health Special Interest Group (SIG) is to serve as the leading convening body across APhA and the profession to promote and advance the role of the pharmacist in public health. The group aims to accomplish these goals through its work: highlight the role of the pharmacist in public health; expand practice models that demonstrate the impact of the pharmacist in public health; strengthen workforce development opportunities for pharmacists interested in public health, including education and postgraduate training; and convene health care partners to advance the role of the pharmacist in population health.

Interested in getting involved in the Public Health SIG? Learn more at apha.us/PHSIG. ■

Advocacy

Created by E. Michael Murphy, PharmD, MBA, APhA advisor for state government affairs, this easy-to-reference map (apha.us/TestandTreatMap) breaks down current states' authorization and payment for test, treat, and immunization services by pharmacists. Please use this valuable resource to advocate in meetings with your elected officials to support our federal legislation, the Equitable Community Access to Pharmacist Services (ECAPS) Act. See apha.us/ECAPSinfo for more information. ■

Did you know?

Elevate your well-being this holiday season with the WBI for Pharmacy Personnel

With the end-of-year holidays coming up, take some time to discover a refreshed approach to self-care with the Well-Being Index (WBI) for Pharmacy Personnel.

This free and online self-assessment tool was invented by the Mayo Clinic and is proudly offered by APhA. It evaluates stress, fatigue, burnout, and anxiety while measuring nine dimensions of distress. By simply answering a few short questions, you can discover your well-being scores and gain access to valuable resources. This investment in yourself will not only positively impact your personal health, but also elevate the quality of care you provide to your patients.

Get started now at www.pharmacist.com/WBI. ■

Offering timely communication: An OTC update

Kelly L. Scolaro, PharmD, pharmacy manager, Good Samaritan Pharmacy & Health Services, Nokomis, FL, and associate editor, *Handbook of Nonprescription Drugs*, 21st Edition

There are an estimated 100,000 to 300,000 OTC products on the market in the United States.[1] The market is constantly changing as new products are introduced, products are reformulated, and in some cases, products are removed. Changes also occur when FDA re-examines rules and responds to consumer concerns about products.

This year, FDA engaged in discussion of a proposed rule for what is referred to as a nonprescription drug product with an additional condition for nonprescription use (ACNU). FDA also approved the first nonprescription daily oral contraceptive and increased access to treatment for opioid overdose by approving OTC naloxone nasal sprays. Lastly, FDA convened an advisory committee to re-examine OTC oral phenylephrine for efficacy and safety. With the approval of new medications and potential changes to rules governing the OTC domain, pharmacists need to be aware of how these developments will impact their professional practice.

Creating new rules: Nonprescription drug product with an ACNU

Currently there are two classes of drugs in the United States: prescription and nonprescription (also referred to as OTC); both classes are regulated by FDA. FDA defines prescription drugs as "any human drug required by Federal law or regulation to be dispensed only by a prescription."[2] Prescription drugs are not considered safe for use except under supervision of a practitioner licensed to administer the drug due to concerns about adverse effects, toxicity, method of use (e.g., infusion), or the need for monitoring (e.g., monitoring kidney or liver function). FDA defines OTC drugs as drugs that "shall be permitted for OTC sale and use by the laity unless, because of its toxicity or other potential for harmful effect or because of the method or collateral measures necessary to its use, it may safely be sold and used only under the supervision of a practitioner licensed by law to administer such drugs."[3]

There are two ways OTC drugs are approved for sale in the United States: OTC monograph and New Drug Application (NDA)/Abbreviated New Drug Application (ANDA). The OTC monograph was established in 1972 and contains a list of OTC drugs that were considered "Generally Recognized As Safe and Effective" based on information that the FDA advisory panels had at that time.[4] Drugs that do not meet the conditions outlined in the monograph go through the NDA or ANDA process.

Regardless of how a drug is approved by FDA to be marketed and sold as OTC, the product must contain a drug facts label (DFL).[5] The DFL is standardized by FDA and is intended to help enable consumers to appropriately self-select and use the nonprescription drug product safely and effectively.[5] However, there are limitations to the DFL, including space constraints and patients' health literacy.

Because of these limitations, since 1984, there have been calls and debate about establishing a third class of drugs. This class of drugs, also known as "behind the counter," would be FDA-approved drugs that were available only from licensed pharmacists.[6] Many people think this third class of drugs already exists, since insulins, syringes, and pseudoephedrine are approved for OTC sales by FDA, but regulations require that they be kept behind the counter. However, this is not the case.

FDA has officially discussed these issues since 2012. In June 2022, FDA published the proposed rule change entitled Nonprescription Drug Product with an ACNU.[7] A public comment period ensued and in February 2023, FDA hosted a public continuing education webinar on the proposed rule which highlighted how the ACNU process would work within the drug

Learning objectives

At the conclusion of this knowledge-based activity, the pharmacist will be able to:

- Identify recent relevant updates to the OTC product domain.
- Discuss implications of recently converted prescription to OTC products on pharmacists.
- Highlight the role pharmacy personnel can play to ensure OTC products are used safely and effectively.
- Describe the FDA's Proposed Rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use.
- Explain how the introduction of new labeling rules may impact the role of the pharmacist.

Preassessment questions

Before participating in this activity, test your knowledge by answering the following questions. These questions will also be part of the CPE assessment.

1. A drug may be approved for nonprescription (i.e., OTC) use by FDA by which of the following?

a. Federal registration
b. Abbreviated New Drug Application
c. Citizen's petition
d. Selective Service application

2. Which of the following statements is correct about the Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU) rule?

a. The rule was finalized by FDA in 2023.
b. The rule creates a third class of drugs.
c. The rule requires patients to purchase OTC products directly from a pharmacist.
d. The rule creates an additional step for patients to complete in addition to the drug facts label prior to purchase.

3. Which active ingredient does the first FDA nonprescription oral contraceptive contain?

a. Norethindrone
b. Norgestrel
c. Nordrospirenone
d. N-ethyl estradiol

approval process and how it aims to address limitations of labeling for OTC drug products.[8]

It is important to note that the proposed rule does not create a third class of drugs. The rule also does not apply to currently marketed OTC drugs that have already been approved by the OTC monograph or NDA/ANDA process. Rather, the proposed rule changes how manufacturers using the NDA/ANDA process could self-identify their product or be instructed by FDA to provide more than just the standard DFL for their product to be considered safe and effective for OTC use.[8]

An example offered in the webinar included the label containing a list of questions the patient would answer to determine if the product was appropriate for them. The patient would submit answers via a kiosk in the pharmacy, a mobile app, toll-free phone number, or secure website. Based on the answers provided, the patient would be informed if the product should be purchased or not. The ACNU rule does not mandate that a patient speak with a pharmacist, but if the rule is finalized pharmacists will most likely be asked to help navigate the ACNU process and answer questions. Also, if a kiosk or other physical item is to be used to answer ACNU-related questions, pharmacists will need to address space and placement concerns.

The Figure outlines what the nonprescription drug approval process would look like if the new rule is finalized by FDA.

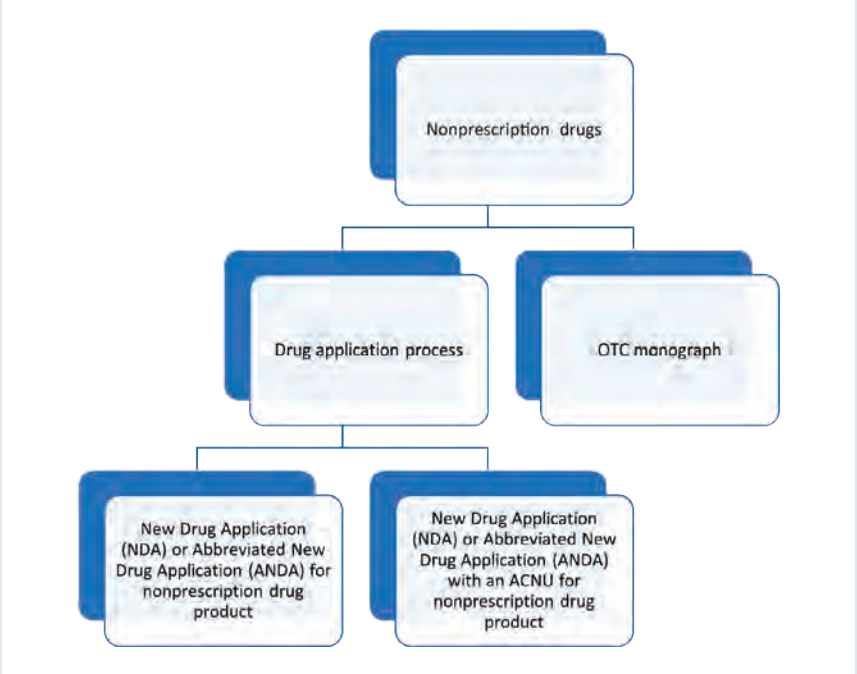
Regarding Rx-to-OTC switch NDA/ANDA applications, the proposed rule allows the manufacturer to continue marketing their prescription products without the additional condition as long as there is no meaningful difference between the prescription product and ACNU product.

The Consumer Products Association (CHPA) and several legislators support the proposed rule, except for its allowance of simultaneous marketing. CHPA is against allowing manufacturers to market a product for both prescription and nonprescription use, as they are concerned about consumer confusion and undermining of the Rx-to-OTC switching process.[9]

The status of a product factors into cost to the patient and also reimbursement to the pharmacy. If the product is filled as a prescription and billed through the patient's insurance company, the patient may incur zero out-of-pocket cost or need to pay a copay, which may or may not be less expensive than paying for the OTC item and not using insurance. Patients may also falsely believe that the prescription product is stronger or safer than the nonprescription product despite the active ingredients and dosage being exactly the same. Because the ACNU as written does not change the fact that a product can be marketed both ways, pharmacists will need to be prepared to have discussions about costs, efficacy, and safety with patients.

FDA has not stated if or when the proposed ACNU rule would be approved and placed into effect. Although the comment period has closed, it is important for pharmacy personnel to be aware that such a rule is being discussed and, if the rule is approved, how the changes will be implemented in practice.

Figure. FDA nonprescription drug product approval process if the ACNU proposed rule is finalized



Adapted from: Walther E. Overview of proposed rule: Nonprescription Drug Product with an Additional Condition for Nonprescription Use. Silver Spring, MD: FDA. Available at: www.fda.gov/media/165784/download. Accessed October 27, 2023.

New OTC drug approvals

Naloxone

Naloxone is a rapid-acting reversal agent of the effects of opioid overdose. Opioid overdose is a medical emergency and will cause symptoms such as extreme somnolence, respiratory depression, bradycardia, hypotension, miosis, and in some cases cardiac arrest and death. Naloxone was first available as a prescription injectable. The nasal spray was developed and approved by FDA in 2015.[10] The prescription nasal spray has been available in 2 mg, 4 mg, and 8 mg dosages.

Even though naloxone nasal spray was prescription-only, by August 2020, all 50 states had passed legislation to allow first responders and public use of naloxone nasal spray without a prescription due to increasing numbers of opioid overdoses.[11]

As opioid overdoses reached epidemic proportions, FDA created an Overdose Prevention Framework.[12] The four priorities of the framework include: "(1) supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; (2) encouraging harm reduction through innovation and education; (3) advancing development of evidence-based treatments for substance use disorders; and (4) protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks."[12]

As part of priority 3, on March 29, 2023, FDA approved naloxone HCl 4 mg nasal spray for nonprescription use.[13] Following that, FDA approved naloxone HCl 3 mg nasal spray on July 28, 2023.[14]

It is important to note that injectable naloxone and the high-dose naloxone nasal spray (8 mg) will still be available by prescription. In addition, nalmefene nasal spray (2.7 mg) is also available by prescription only.[15] Table 1 provides a summary of opioid reversal nasal spray products.

The OTC 4 mg naloxone product is on shelves now and can be accessed at places like drug stores, convenience stores, grocery stores, and gas stations as well as online. The approximate cost according to the manufacturer's website is $45.[16] The 3-mg nasal spray is expected to be available in 2024.[17]

Patients and caregivers must understand that naloxone will have no effects if a patient's overdose symptoms are not due to opioids, and the reversal effects are limited in cases of partial agonists or mixed agonist/antagonists such as buprenorphine. Also, illicit use of novel potent opioids such as brorphine, isotonitazene, and especially metonitazene may require higher doses of naloxone.[18] Also, it is critical to note that each nasal spray unit is one-time-use only and should not be opened or primed prior to administration.

Medical emergency assistance should be called after the first dose of naloxone is administered. Administration of naloxone may cause sudden opioid withdrawal syndrome, especially in patients who have been using opioids regularly or for a long period of time. This syndrome manifests itself in a variety of ways including sweating, shivering, increased blood pressure and pulse, body aches, nausea/vomiting/diarrhea/abdominal pain or cramping, irritability, restlessness, and anxiety. Other adverse effects associated with naloxone nasal spray include headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.[16]

Although FDA has designed, tested, and validated a model naloxone DFL with easy-to-understand pictograms on how to use the drug, pharmacists and pharmacy technicians will need to be ready to answer questions and provide guidance on best practice for use in the community setting. Shelf space for naloxone products and information will need to be created, and discussions on the ideal placement within the pharmacy will be needed. Pharmacists and pharmacy technicians can also proactively pro-

Table 1. Opioid reversal agent nasal sprays

Drug name	Dosage form	Dosing information	Prescription or non-prescription status	Product website
Nalmefene hydrochloride	Nasal spray	2.7 mg intranasal. For patients 12 years and older. Administration of a single spray intranasally into one nostril. Administer additional doses of nasal spray, using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression. Additional doses of nasal spray may be given every 2 to 5 minutes until emergency medical assistance arrives.	Prescription	https://opvee.com
Naloxone hydrochloride	Nasal spray	3 mg intranasal. No age restrictions. Administration of a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Nonprescription	www.harmreduction-therapeutics.org/
Naloxone hydrochloride	Nasal spray	4 mg intranasal. No age restrictions. Administration of a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Prescription and non-prescription	https://narcan.com
Naloxone hydrochloride	Nasal spray	8 mg intranasally. No age restrictions. Administration of a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if the patient does not respond or responds and then relapses into respiratory depression. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Prescription	https://kloxxado.com/

vide naloxone product information to patients and caregivers when filling opioid prescriptions.

Besides having naloxone on hand, opioid users may also need other types of support such as mental health counseling. Pharmacists and pharmacy technicians can use Substance Abuse and Mental Health Services Administration website www.samhsa.gov to provide referrals for treatment and counseling.

Norgestrel

Pregnancy rates have been declining in the United States in recent years; however, unintended pregnancies still occur. CDC reported the unintended pregnancy rate was approximately 36% (per 1,000 women aged 15–44) in 2019.[19]

Prescription oral contraceptives containing estrogen/progesterone or progesterone only have been available since the 1960s. When taken daily, they prevent pregnancy by preventing ovulation.

Emergency contraceptive pills help prevent pregnancy if intercourse occurred without using a contraceptive, if the contraceptive method failed, and in cases of sexual assault. Emergency contraceptive pills contain estrogen/progesterone or progesterone only and, when taken within 72 hours of unprotected intercourse, pregnancy is prevented by stopping the release of the egg from the ovary and by blocking sperm's access to the egg. Prescription emergency contraceptive pills were approved by FDA in 1998.[20] Since June 20, 2013, levonorgestrel has been available OTC for emergency contraception without age restrictions.[20]

On July 13, 2023, FDA approved norgestrel tablets for nonprescription use to prevent pregnancy.[21] Norgestrel is not approved as emergency contraception; rather, it is meant to be taken daily to prevent pregnancy. According to the manufacturer, the nonprescription carton will contain 28 norgestrel 0.075 mg tablets.[22]

Norgestrel can be started at any time during the menstrual cycle, but if it is not started on the first day of the patient's menstrual period, condoms should be used for 2 days. Due to pharmacokinetics of progestin-only

Table 2. Progestin-only oral contraceptives

Generic name	Dosage	Prescription or nonprescription
Drospirenone	4 mg/tablet; 24 tablets and 4 placebo tablets (total 28 tablets)	Prescription
Levonorgestrel	1.5 mg/tablet; 1 tablet	Nonprescription
Norethindrone	0.35 mg/tablet; 28 tablets	Prescription
Norgestrel	0.075 mg/tablet; 28 tablets	Nonprescription

pills, pharmacists need to stress to patients to take norgestrel at the same time (i.e., within 3 hours) every day to ensure contraceptive effects.[22] If norgestrel is taken outside of the 3-hour window or missed altogether, patients should resume the dose and use a backup method of contraception (e.g., condom) for 48 hours after the late or missed dose.

Norgestrel is usually well-tolerated but may exacerbate migraine headaches or cause abnormal menstrual bleeding, breast discomfort, or nausea. Patients with seizures, tuberculosis, HIV/AIDS, or pulmonary hypertension should be encouraged to speak to a pharmacist before starting norgestrel to check for drug–drug interactions, as norgestrel interacts with strong CYP3A4 inducers. Patients should also be reminded that norgestrel does not protect against HIV or other STDs. Pharmacy staff may want to stock norgestrel and condoms together and perhaps even have signage with this reminder.

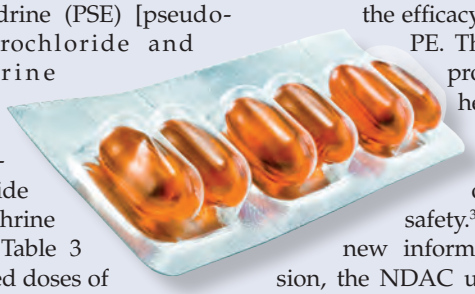
Providers should note that progestin-only oral contraceptives will still be available via prescription (Table 2).[23]

Patients may have questions about switching from prescription to nonprescription oral contraceptives, including insurance coverage and cost implications. Pharmacists need to be prepared to discuss these issues with patients. If pharmacists need sources for in-depth drug information and counseling, The U.S. Selected Practice Recommendations for Contraceptive Use and the U.S. Medical Eligibility Criteria for Contraceptive Use are two helpful guidelines.[24,25]

The approval of a daily nonprescription oral contraceptive will allow consumers the convenience of purchasing at drug stores, convenience stores, and grocery stores as well as online. Patients should still be encouraged to see a health care provider for regular screenings (e.g., PAP smears and mammograms). Although the timeline for availability and the price are yet to be determined, pharmacists and pharmacy technicians will need to be prepared to answer questions, provide guidance to patients and consumers on proper ways to take the medication, and where to access it.

Old controversy, new data: FDA Advisory Committee examines efficacy and safety of oral phenylephrine

Currently, the only oral decongestants available OTC in the United States are pseudoephedrine (PSE) [pseudoephedrine hydrochloride and pseudoephedrine sulfate] and phenylephrine (PE) [phenylephrine hydrochloride and phenylephrine bitartrate]. (See Table 3 for FDA-approved doses of oral PSE and PE and examples of oral decongestant products currently on the market.[26]) These products are approved for OTC use under the 1972 OTC monograph process.



Due to the development of the methamphetamine crisis, PSE is highly regulated. PSE products must now be kept in secure areas (e.g., behind a pharmacy counter or in a locked cabinet), and purchases are limited to 3.6 g daily and 9 g per month per patient.[27] The following information from each sale must be entered into a paper or electronic logbook: product name, quantity sold, patient's name and address, and time and date of sale.[27] Patients must show valid identification to purchase PSE and then sign the logbook. Some states and corporations have enacted stricter guidelines regarding the sale of PSE.

In response to the restrictions, many manufacturers reformulated products that remove PSE and add PE instead. PE's effectiveness as a topical decongestant delivered via nasal spray or drops has not been questioned. In contrast, the efficacy and safety of PE as an oral decongestant has long been questioned due to its short half-life and extensive first-pass metabolism. Citizens petitions have been filed urging FDA to remove oral PE from the OTC monograph, which would in turn require manufacturers to either reapply for approval using the NDA/ANDA process or remove their oral PE products from the market.[28]

In response to the controversy and the citizens petitions, FDA convened the Nonprescription Drugs Advisory Committee (NDAC) on December 14, 2007, and the NDAC recommended more studies be conducted on oral PE.[29] FDA reconvened the NDAC on September 11–12, 2023, to examine the results of the new studies and vote on the efficacy and safety of oral PE. The NDAC meeting provided a comprehensive look at the history of PE and all data available on efficacy and safety.[30] Based on the new information and discussion, the NDAC unanimously voted (16–0) that oral PE is not efficacious at current FDA-approved doses and recommended to FDA that it be removed from the OTC monograph.[30] The NDAC did not find any safety issues with oral PE.[30,31]

FDA is not bound by the NDAC recommendations in their consideration of removing oral PE. CHPA opposes

Table 3. Phenylephrine and pseudoephedrine dose and product information

Drug	Dosage[a] (maximum daily dose)		
	Adults and children >12 years	Children 6 to <12 years	Children 2 to <6 years[b]
Phenylephrine HCl	10 mg every 4 hours (60 mg)	5 mg every 4 hours (30 mg)	2.5 mg every 4 hours (15 mg)
Phenylephrine bitartrate	15.6 mg every 4 hours (62.4 mg)	7.8 mg every 4 hours (31.2 mg)	Not recommended for children <6 years except under advice of HCP
Pseudoephedrine HCl or sulfate	60 mg every 4–6 hours (240 mg)	30 mg every 4–6 hours (120 mg)	15 mg every 4–6 hours (60 mg)
Example single-ingredient products			
Sudafed PE Sinus Congestion	Phenylephrine HCl 10 mg	—	—
Sudafed Sinus Congestion 24 Hour	Pseudoephedrine HCl 240 mg	—	—
Sudafed Sinus Congestion 12 Hour	Pseudoephedrine HCl 120 mg	—	—
Nexafed	Pseudoephedrine HCl 30 mg	—	—
Zephrex-D	Pseudoephedrine HCl 30 mg	—	—
Example combination products			
Sudafed PE Sinus Pressure + Pain	Phenylephrine HCl 5 mg, acetaminophen 325 mg		
Alka-Seltzer Plus Severe Cold	Phenylephrine bitartrate 7.8 mg, aspirin 325 mg, chlorpheniramine maleate 2 mg		
Vicks Dayquil Cold & Flu Relief Liquicaps	Phenylephrine HCl 5 mg, acetaminophen 325 mg, dextromethorphan hydrobromide 10 mg		
Tylenol Cold + Flu + Cough Nighttime Liquid	Phenylephrine HCl 5 mg/15 mL, acetaminophen 325 mg/15 mL, dextromethorphan hydrobromide 10 mg/15 mL, doxylamine succinate 6.25 mg/15 mL		
Mucinex Children's Multi-Symptom Cold Liquid	Phenylephrine HCl 2.5 mg/5 mL, guaifenesin 100 mg/5 mL, dextromethorphan hydrobromide 5 mg/5 mL		
Aleve-D Sinus & Cold	Pseudoephedrine HCl 120 mg, naproxen sodium 220 mg		
Mucinex D	Pseudoephedrine HCl 60 mg, guaifenesin 600 mg		

[a] Taken as needed.
[b] FDA has advised that cough and cold medications not be used in children younger than 2 years old. Manufacturers voluntarily updated cough and cold product labels to state "do not use" in children younger than 4 years old.
Abbreviations: HCl, hydrochloride; HCP, health care provider.

removal of oral PE from the market and presented at the NDAC meeting.[32] CHPA also released a statement after the NDAC recommendations were published urging FDA to consider all data and implications of removal of oral PE from the market.[32] FDA has not published a timeline for ruling on the NDAC recommendation.

In October 2023, one large pharmacy retailer stated it was voluntarily removing monotherapy oral PE products from shelves but continues to market and sell combination products containing PE.[33]

The NDAC vote and the PE controversy has received a lot of media attention, and the public has many questions. Pharmacists and pharmacy technicians can help patients with those questions and enable patients to purchase the best decongestant for their specific symptoms.

In summary, there have been many changes to the United States nonprescription drug market in 2023. The ACNU rule, if approved, will most likely cause a large shift in future OTC product labeling, marketing, and even physical placement in stores. The ACNU rule offers an expanded opportunity for drug manufacturers and pharmacists to engage patients in a dialogue to ensure they are selecting an OTC product that is not only safe, but also effective based on the patient's individual health circumstances. The approval of new OTC products such as naloxone and norgestrel, and the controversy over the efficacy of oral PE and voluntary removal of PE from some stores, also create opportunities for pharmacy staff to engage patients in discussions about accessibility, costs, and efficacy.

Pharmacists and pharmacy technicians should stay tuned to APhA and FDA for important decisions on ACNU, more Rx-to-OTC switches, and the ongoing oral phenylephrine controversy.

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Accreditation information

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ACPE Universal Activity Number: 0202-0000-23-425-H01-P
CPE credit: 1 hour (0.1 CEU)
Fee: There is no fee associated with this activity for APhA members. There is a $25 fee for nonmembers.

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CPE information

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CPE Assessment

This assessment must be taken online; please see "CPE information" in the sidebar on the previous page for further instructions. The online system will present these questions in random order to help reinforce the learning opportunity. There is only one correct answer to each question.

1. A drug may be approved for nonprescription (i.e., OTC) use by FDA by which of the following?
a. Federal registration
b. Abbreviated New Drug Application
c. Citizen's petition
d. Selective Service application

2. Which of the following statements is correct about the Nonprescription Drug Product with an Additional Condition for Nonprescription Use (ACNU) rule?
a. The rule was finalized by FDA in 2023.
b. The rule creates a third class of drugs.
c. The rule requires patients to purchase OTC products directly from a pharmacist.
d. The rule creates an additional step for patients to complete in addition to the drug facts label prior to purchase.

3. Which of the following statements is correct about the Nonprescription Drug Product with an ACNU rule?
a. The rule will allow a drug to be simultaneously marketed as prescription and nonprescription.
b. The rule will replace the OTC monograph.
c. The rule will make Rx-to-OTC switches more difficult.
d. The rule will force manufacturers to relabel products already on the market.

4. FDA first approved naloxone nasal spray as a nonprescription product in which of the following strengths?
a. 2 mg
b. 4 mg
c. 6 mg
d. 8 mg

5. How many priorities does the FDA Overdose Prevention Framework contain?
a. 1
b. 2
c. 3
d. 4

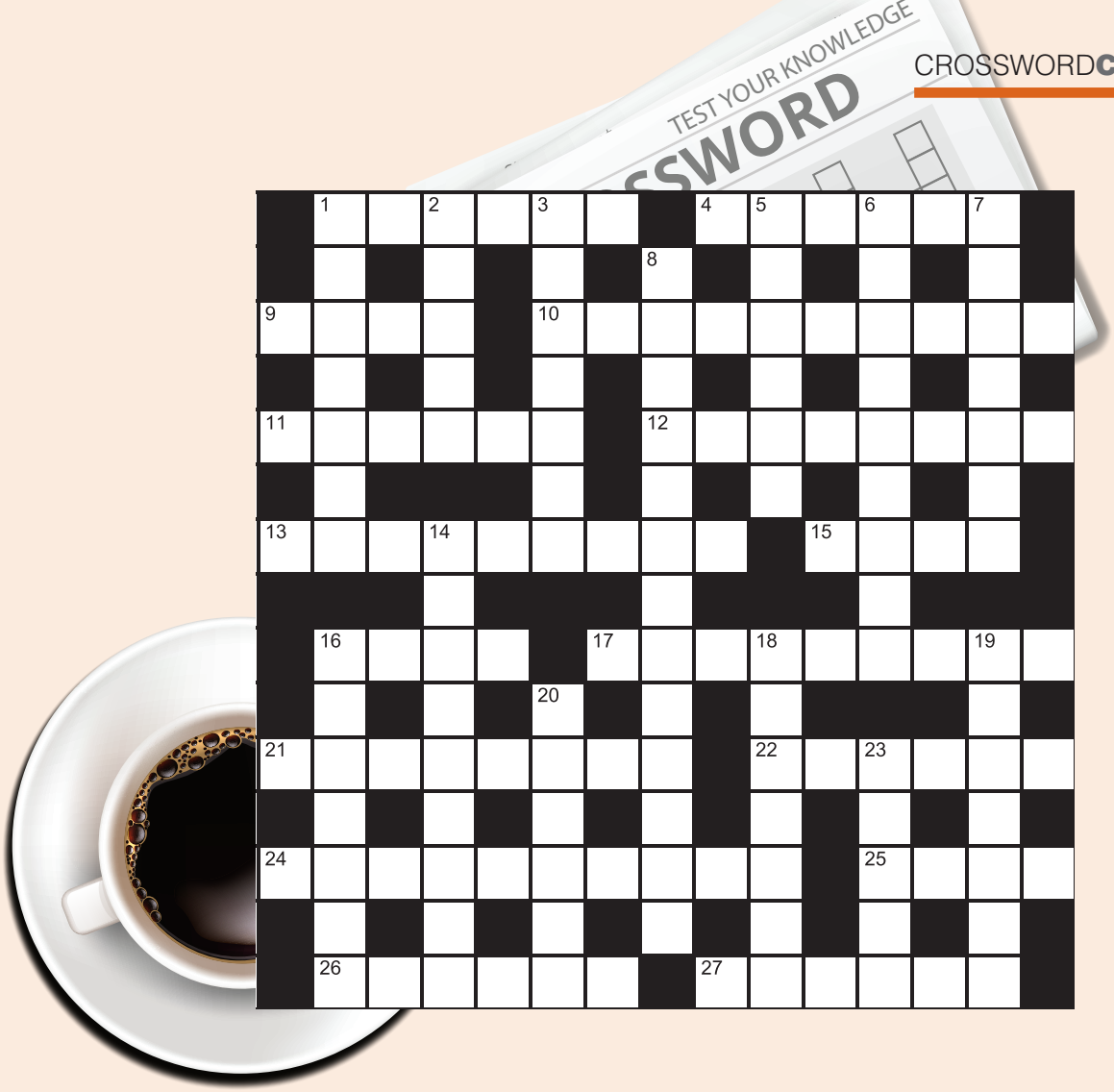
6. Which of the following is correct about naloxone nasal spray?
a. The correct dosing is one spray in each nostril.
b. The nasal spray may cause sudden opioid withdrawal syndrome.
c. There is no need to call for medical attention if the nasal spray is used successfully.
d. The nasal spray should be primed once before administration.

7. Which of the following is an action that pharmacy personnel can take to ensure the newly approved OTC oral contraceptive product is used safely and effectively?
a. Discuss the time-sensitive nature of the product and encourage the patient to take the product at the same time every day.
b. Place the oral contraceptive product on or near shelves containing condoms and post signage reminding patients that the product does not protect against HIV or STDs.
c. Ask patients about other medical conditions such as seizures and prescription drugs they are taking prior to selling the oral contraceptive product.
d. All of the above.

8. Which active ingredient does the first FDA nonprescription oral contraceptive contain?
a. Norethindrone
b. Norgestrel
c. Nordrospirenone
d. N-ethyl estradiol

9. FDA approved phenylephrine for nonprescription use via which of the following procedures?
a. Federal Register
b. Abbreviated New Drug Application
c. Citizen's petition
d. OTC monograph

10. Which of the following statements is correct regarding the outcome of the NDAC meeting that was held in September 2023?
a. The NDAC voted that oral phenylephrine was not effective at current approved doses.
b. All phenylephrine products must be removed from the market by the end of 2023.
c. The NDAC voted that oral phenylephrine was not safe to use at current approved doses.
d. All of the above.



Across

1 Book jacket bits
4 Cut back, as a dosage
9 Attention ___
10 Name for a pharmacist derived from ancient Greek
11 Flushed, as in facial complexion
12 Tear
13 Recommends the use of, as for a medication
15 Latin abbreviations for drugs delivered by this route can be confusing (AU, AS, AD)
16 Adderall target, briefly
17 Originally developed as an antidepressant but low doses help insomnia
21 A vitamin, mineral, or protein, among others
22 Vitamin B3
24 Colds and coughs can cause this in kids
25 Waste product of mammals
26 Cause of hereditary variation
27 Disease-carrying fly

Down

1 Can be associated with extreme mood swings
2 _____ nerve ("funny bone")
3 Organ that stores urine
5 Pharmacists commit to a code of these
6 Developed into an inflamed and painful sore
7 Inconsistent
8 Working together, as physicians and pharmacists
14 Globular, like a ball
16 In some forms, ingredient in some antiperspirants
18 High points
19 Gullibility based on inexperience
20 Topical drugs are administered by this route
23 Many medications are formulated only for _____ patients

Solution is available online at pharmacytoday.org.