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Vaccines Coronavirus vaccine development
Respiratory Pipeline of potential COVID-19 therapies
Health Systems Cancer care during the pandemic
Are your pharmacy customers demanding “touchless delivery”?

As the number of coronavirus cases continues to rise in the U.S. and consumers increasing isolate themselves as a preventive measure, touchless delivery is likely to become a standard delivery practice.

— Forbes, March 16, 2020

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EDITORIAL MISSION: Drug Topics is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
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Arm Yourself With Information During the COVID-19 Pandemic

Response efforts to the global pandemic of the novel coronavirus disease 2019 (COVID-19) have kicked into high gear over the past several weeks. Never before have we seen the health care community come together in such a concerted effort in the search for potential treatments and vaccines. And in the face of COVID-19, pharmacists continue to provide accessible care to patients.

However the pandemic unfolds over the next few months, one thing is certain: COVID-19 will likely have a ripple effect for a long time to come. At Drug Topics®, we aim to deliver the most timely and relevant news and information to help you better serve your patients during times of crisis. In this issue, you’ll discover some of the investigative therapies and vaccines in the pipeline for COVID-19.

Just as expected, pharmacies have demonstrated meaningful ways to support their communities in difficult times. Although many people are working from home these days, pharmacies continue to operate as essential businesses to ensure patients get the medications they need. On page 27, Jenni Zilka, senior vice president at Good Neighbor Pharmacy Field Programs & Services, AmerisourceBergen, writes about some of the ways in which community pharmacies are enhancing their communication with patients during this time.

Our cover story looks into the cutting-edge innovation happening right now in the industry. Technology will drastically transform pharmacy, with products involving artificial intelligence, automation, and real-time data analytics. This story dives into how up-and-coming digital health products are closing the gaps and connecting the dots in health care like never before.

Check out our Careers section for more insights focused on different aspects of the pharmacy profession. On page 13, Frieda Wiley, PharmD, discusses the pharmacist’s role in managing cardiovascular disease in patients. On page 11, you’ll learn more about how pharmacy schools are preparing their students for specific population challenges, such as working in pharmacy deserts.

In addition, MJH Life Sciences, parent company of Drug Topics®, has launched a 24-hour online news network for health care professionals to bring you live updates and interviews with leading experts. The program is a great opportunity to dig into cross-specialty feedback for multidisciplinary approaches to treatments and guidelines. Visit mjhlifesciences.com/news-network to tune in.

Thank you for reading and continue to follow us on drugtopics.com for the latest news.

Mike Hennessy, Sr.
Chairman and Founder of MJH Life Sciences™
FDA Requests Removal of All Ranitidine From Market

In April, the FDA requested that manufacturers of all ranitidine (Zantac) drugs, both prescription and OTC, remove their products from the market, according to a press release.1 Because of this market withdrawal request, ranitidine products will not be available for new or existing prescriptions or OTC use in the United States.

As a result of its ongoing investigation into traces of N-nitrosodimethylamine found in some ranitidine medicines, the FDA is urging immediate market withdrawal due to its findings. The agency has determined that the impurity in some ranitidine products increases over time, even under normal storage conditions, and when stored at higher than room temperature. This may result in consumer exposure to unacceptable levels of this impurity.

In addition, the FDA announced its intent to send letters to all manufacturers of ranitidine requesting that they withdraw their products from the market. Further, the FDA is advising consumers to stop taking OTC ranitidine and to dispose of the medication properly. Patients taking prescription ranitidine are encouraged to speak with their health care professional about other treatment options before stopping the medicine. ■
Two new studies suggest an association between opioid prescriptions and obesity in the United States. According to the first study, published in the *American Journal of Preventive Medicine*, obesity contributes significantly to incident long-term prescription opioid use.1,2 The investigators analyzed data from 89,629 adults aged 30 to 84 years who were prescription opioid–naive for approximately 9 months. Among opioid-naive adults, obesity was strongly associated with incident long-term prescription opioid use, according to the study.1

Joint pain, back pain, injury, and muscle/nerve pain were identified as the highest contributors to the excess use of opioids observed among adults with obesity.1

The second study, published in *JAMA Open Network*, looked at the pain conditions underlying this increased likelihood of opioid prescriptions for individuals with a higher body mass index (BMI). For the study, the investigators analyzed electronic health records of 565,930 patients to determine the association between obesity and pain diagnoses recorded as reasons for opioid prescriptions.2

Among the patients in the study, the risk of receiving prescription opioids increased progressively with a higher BMI, and the percentage of patients with opioid prescriptions attributable to an overweight or obese BMI was 16.2% (95% CI, 15.0%-17.4%).2 Osteoarthritis, other joint disorders, and other back disorders were the most prominent pain diagnoses associated with increased prescribing of opioids to patients with obesity, according to the findings.2

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**FDA Approves Treatment for Hemophilia A or B With Inhibitors**

The FDA has approved another option for the treatment and control of bleeding episodes in adults and in adolescents 12 years and older with hemophilia A or B with inhibitors, according to a press release.1

Coagulation factor VIIa (recombinant)-jncw (Sevenfact, LFB) is the first product for hemophilia treatment that contains an active ingredient obtained from rabbits genetically engineered to produce a protein necessary for blood coagulation, according to the FDA. The active ingredient is a recombinant analogue of human FVIII, which is expressed in the mammary gland of genetically engineered rabbits and secreted into their milk, where it is converted into activated FVII.

A clinical study including 27 patients with hemophilia A or B with inhibitors and the treatment of 465 mild or moderate and 3 severe bleeding episodes evaluated the safety and efficacy of coagulation factor VIIa (recombinant)-jncw. The efficacy of the treatment was evaluated 12 hours after the initial dose was given. According to the results, the proportion of mild or moderate bleeding episodes treated successfully with both the lower dose of 75 µg/kg and the higher dose of 225 µg/kg (requiring no further treatment for the bleeding episode and no administration of blood products, and with no increase in pain beyond 12 hours from initial dose) was approximately 86%.1

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**FDA OKs Ixekizumab for Pediatric Patients With Plaque Psoriasis**

The FDA has granted approval to ixekizumab (Taltz, Eli Lilly) injection, 80 mg/mL, for the treatment of pediatric patients with moderate to severe plaque psoriasis, according to a press release.1 With this approval, ixekizumab is the first IL-17A available for the treatment of this population, said Eli Lilly.

This expanded pediatric indication was based on data from a phase 3 study that included 171 patients aged 6 to under 18 years with moderate to severe plaque psoriasis.1
DEA Deschedules Antiepileptic CBD Oral Solution Epidiolex

The US Drug Enforcement Administration (DEA) has descheduled GW Pharmaceuticals’ antiepileptic cannabidiol (CBD) oral solution (Epidiolex), making it no longer subject to the Controlled Substances Act, the company announced.\(^1\) The DEA’s letter means that all federal controlled-substance restrictions have been removed for the product. Once these changes have been implemented, all prescriptions for CBD oral solution will be valid for 1 year and can be easily transferred between pharmacies. Additionally, these changes will enable physicians to prescribe the medicine free of the requirements of state prescription drug monitoring programs.\(^1\)

Rimegepant Demonstrates Efficacy in Prevention of Migraine

Oral rimegepant demonstrated significant superiority compared with placebo in reducing monthly migraine days, according to results from a clinical trial.\(^2\) Rimegepant (Nurtec ODT, Biohaven Pharmaceuticals), a calcitonin gene-related peptide (CGRP) receptor antagonist, is approved for the acute treatment of migraine in adults with or without aura. However, it is not currently indicated for the preventive treatment of migraine. The study evaluated the efficacy and safety of oral rimegepant 75 mg for the preventive treatment of migraine in patients with both episodic and chronic migraine. Patients included in the study had migraine for at least 1 year and 4 to 18 moderate to severe migraine attacks per month over 3 months prior to enrollment. Rimegepant 75 mg was dosed every other day versus placebo. According to the results, patients treated with rimegepant demonstrated a statistically significant reduction from baseline in monthly migraine days compared with placebo, meeting the study’s primary end point. Rimegepant is the first CGRP-targeting therapy to complete pivotal trials that demonstrates its efficacy in both the acute and preventive treatment of migraine.\(^2\)

Many Community Pharmacists Reporting Drug Shortages

The National Community Pharmacists Association (NCPA) announced the results from a recent survey, that found that nearly 90% of neighborhood pharmacies have experienced drug shortages since March 1, 2020, according to a press release.\(^1,2\) As the United States health care system wears thin in the face of coronavirus disease 2019 (COVID-19), the survey asserted that the drugs being used to fight the virus are among the scarcest, according to local pharmacies. Among the most common drug shortages reported by neighborhood pharmacists were albuterol inhalers, hydroxychloroquine, and azithromycin, as well as others that have seen spikes in demand since the outbreak began.\(^2\) The NCPA survey showed that more than half of neighborhood pharmacies plan to perform point-of-care COVID-19 testing once it is available. Pharmacists have also taken additional steps to aid in the pandemic, including compounding hand sanitizer to donate to first responders and hospitals, where it is needed most.\(^1\)

President Trump Announces 3-Phase Reopening Plan for States

President Donald J. Trump announced his 3-phase proposed plan for reopening US state economies amid the coronavirus disease 2019 (COVID-19) pandemic.\(^1\) Although the steps are geared toward reopening through these 3 phases, state and local officials may need to tailor the application of the guidance to local circumstances, especially in areas hit particularly hard by the pandemic. Before they can proceed with reopening, states must be able to satisfy certain gating criteria. For instance, there must be a reported downward trajectory of influenza-like illnesses, COVID-19-like syndromic cases, documented cases, and positive tests as a percentage of total tests within a 14-day period. In addition, hospitals must be able to treat all patients without crisis care and have a robust testing program in place for at-risk health care workers.\(^1\)
Pharmacy Job Demand Could Grow Because of COVID-19

By Christine Blank

The growing recognition of the importance of pharmacists and pharmacy staff on the front lines of the novel coronavirus disease 2019 (COVID-19) pandemic could draw more students to the profession.

Already, there is a heightened demand for retail pharmacists and pharmacy technicians. Soon after the pandemic hit the United States in mid-March, CVS said it would immediately fill 50,000 full-time, part-time, and temporary roles in its stores across the country.1

“We have many open positions for pharmacists, technicians, and workers with health care training,” Joseph Goode, senior director of corporate communications for CVS Health, told Drug Topics at the time. Although Goode declined to reveal how many pharmacy-related jobs would be filled, there were numerous postings for pharmacists, pharmacy managers, pharmacy techs, and related positions on the CVS website.

Walgreens said it would seek to fill more than 9500 existing full-time, part-time, and temporary roles in stores across the United States.2 The company began offering a 1-time bonus for all hourly employees of $300 for full-time workers and $150 for part-time workers in late April.2

In addition, Amazon is expected to hire some pharmacists as part of its national hiring spree of 100,000 individuals, Lucinda L. Maine, PhD, RPh, executive vice president and CEO of the American Association of Colleges of Pharmacy (AACP), told Drug Topics.3

The hiring spree is a stark reversal of the retail pharmacy trend over the past year, which saw many major drugstore chains closing stores and cutting pharmacy staff.

An increase in pharmacy school graduates in the past few years had made it difficult to find jobs. However, the positive press and recognition that pharmacists are receiving during the COVID-19 pandemic should bode well for the profession—and pharmacy schools—in the future.

“There have been major national TV news programs electing to profile various pharmacy stories. We would like to think that a lot of the public misunderstanding or lack of appreciation [for the profession] maybe softened a little bit to the advantage of the profession,” Maine said.

“Pharmacies and pharmacists are offering important services related to COVID-19 and helping patients with other illnesses who are encountering an overwhelmed health care system,” said Steven C. Anderson, IOM, CAE, president and CEO of the National Association of Chain Drug Stores, in a press release.3

Pharmacists’ ability to administer COVID-19 tests gives further recognition to the profession as an important health care provider.

“Pharmacies have taken a role in providing immunizations. Now pharmacy is going to be called on to conduct tests as they become less invasive. The CDC recognizes that pharmacists are skilled in this,” Lynette Bradley-Baker, PhD, RPh, senior vice president of public affairs and engagement at AACP, told Drug Topics.3

Although the surge in positivity for the profession may spur more high school students to pursue careers in pharmacy, it is too early to quantify the trend, Maine said.

“Because of the tremendous uncertainty about higher education in general and the dislocation of pharmacy students, we have not yet seen a turnaround in application to schools for the year that will begin in 2020,” Maine noted. “It is pretty late in the cycle for that."

However, there is speculation that the favorable publicity might attract “a certain type of health profession, preprofession student, who didn’t really think of pharmacy in that way and might think of what it might take to become a pharmacist,” Maine said.

For those who don’t feel comfortable working on the frontlines because of COVID-19, there are many telehealth and online positions that also require pharmacists, Maine added.4

For references, visit drugtopics.com

Career

Lucinda L. Maine, PhD, RPh

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Oral, once-daily, nonstatin

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- **18% mean reduction in LDL-C** (compared to placebo)
  when added to maximally tolerated statin dose (**p=0.001**)  
- Incidence of **skeletal muscle adverse events**
  comparable to placebo

For more information about NEXLETOL, visit NEXLETOLHCP.com

INDICATION
NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

Limitations of Use: The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

**Dosage Form and Quantity:** NEXLETOL is available as an oral tablet containing 180 mg of bempedoic acid, taken once a day with or without food.

**Contraindications:** None.

**Warnings and Precautions:**
- **Hyperuricemia:** NEXLETOL may increase blood uric acid levels. Hyperuricemia may occur early in treatment and persist throughout treatment, and may lead to the development of gout, in patients with a history of gout.
- **Tendon Rupture:** NEXLETOL is associated with an increased risk of tendon rupture, most commonly involving the biceps tendon, rotator cuff, or Achilles tendon. Tendon rupture occurred within weeks to months of starting NEXLETOL. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure and patients with previous tendon disorders.
- **Adverse Events:** In clinical trials, the most commonly reported adverse events were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Events reported less frequently, but still more often than in placebo, included benign prostatic hyperplasia and atrial fibrillation.
- **Laboratory Tests:** NEXLETOL was associated with persistent changes in laboratory tests within the first four weeks of treatment, including increases in creatinine and blood urea nitrogen, decreases in hemoglobin and

**IMPORTANT SAFETY INFORMATION (cont.)**
- **leukocytes,** increases in platelet counts, increases in liver enzymes (AST and/or ALT), and increases in creatine kinase. Laboratory abnormalities generally did not require medical intervention. Laboratory test values generally returned to baseline following discontinuation of treatment.

**Drug Interactions:**
- **Simvastatin and Pravastatin:** Concomitant use results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

**Special Populations:**
- It is not recommended that NEXLETOL be taken during breastfeeding. A pregnant patient should consult with their healthcare provider about whether to continue treatment with NEXLETOL during the pregnancy. The safety and efficacy of NEXLETOL have not been established in patients under the age of 18. Patients over 65 accounted for nearly 60% of patients in clinical trials. No adjustments in dosing are required for age, or for patients with mild or moderate renal or hepatic impairment.

**NEXLETOL is available only by prescription.**

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or ESPERION at 833-377-7633 (833 ESPREMED).

Please see adjacent Brief Summary.

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*LDL-C changes from baseline (LS mean) in CLEAR Harmony: NEXLETOL: -17% (n=1,488); placebo: -2% (n=742).*

CLEAR Harmony (Study 3): a 52-week, randomized, double-blind, Phase 3 trial in 2,230 patients randomized 2:1 to receive NEXLETOL (n=1,488) or placebo (n=742). CLEAR Harmony included patients aged ≥18 years with fasting LDL-C ≥70 mg/dL, and high-risk patients with ASCVD and/or HeFH. NEXLETOL was added to whatever patient’s maximally tolerated statin dose was, either alone or with other lipid-lowering therapies. Primary endpoint was general safety, which included adverse events, clinical safety laboratory, physical examinations, vital signs, and electrocardiogram. Secondary endpoint was % change from baseline to Week 52 in LDL-C.

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Limitations of Use: The effect of NEXLETOL on cardiovascular mortality and mortality has not been determined.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Hyperuricemia: NEXLETOL inhibits renal tubular OAT2 and may increase blood uric acid levels. The data described below reflect exposure to NEXLETOL in two placebo-controlled trials that included a total of 1032 patients treated with NEXLETOL and 1031 patients treated with placebo. Increases in uric acid levels usually occurred within the first 4 weeks of treatment initiation and persisted throughout treatment. After 12 weeks of treatment, the mean placebo-adjusted increase in uric acid compared to baseline was 0.8 mg/dL for patients treated with NEXLETOL. Elevated blood uric acid may lead to the development of gout. Gout was reported in 11% of patients treated with NEXLETOL, and 8% of patients treated with placebo. The risk for gout flare was higher in patients with a prior history of gout (7.2% NEXLETOL versus 1.9% placebo), although gout also occurred in more frequent than placebo treated patients with NEXLETOL who had no prior gout history (10% NEXLETOL versus 0.3% placebo). Advise patients to contact their healthcare provider if symptoms of hyperuricemia occur. Assess serum uric acid when clinically indicated. Monitor patients for signs and symptoms of hyperuricemia, and initiate therapy with urate-lowering drugs as appropriate.

Tendon Rupture: NEXLETOL is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with NEXLETOL versus 0.1% of placebo-treated patients. Tendon rupture may occur more frequently in patients over 60 years of age, in those taking concomitant corticosteroid drugs, with renal failure, and in patients with previous tendon disorders. Discontinue NEXLETOL immediately if the patient experiences rupture of a tendon. Consider discontinuing NEXLETOL if the patient experiences joint pain, swelling, or inflammation. Advise patients to rest at the first sign of tendinitis or tendon rupture and to contact their healthcare provider if tendinitis or tendon rupture symptoms occur. Consider alternative therapy in patients with a history of tendon disorders or tendon rupture.

ADVERSE REACTIONS

The data described below reflect exposure to NEXLETOL in two placebo-controlled trials that included 2009 patients treated with NEXLETOL for 52 weeks (median treatment duration of 52 weeks) and 2011 patients treated with placebo for 52 weeks. NEXLETOL-treated patients were 65% women, 3% Hispanic, 38% White, 3% Black, 1% Asian, and 1% other races. All patients received NEXLETOL 180 mg orally once daily plus maximally tolerated statin therapy alone or in combination with other lipid-lowering therapies. At baseline, 97% of patients had clinical atherosclerotic cardiovascular disease (ASCVD) and about 4% had a history of atherogenic familial hypercholesterolemia (FH). Patients had a mean age of 56 years, 9% had diabetes, 11% had hypertension, and 21% had a history of smoking. The most common reasons for discontinuing treatment were muscle spasms (0.5% versus 0.3% placebo), diarrhea (0.2% versus 0.1% placebo), and pain in extremity (0.3% versus 0.0% placebo). Adverse reactions reported in at least 2% of NEXLETOL-treated patients and more frequently than in placebo-treated patients are shown in Table 1.

Table 1. Adverse Reactions (≥ 2% and Greater than placebo) in NEXLETOL-Treated Patients

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>NEXLETOL + Statin and Other Lipid-Lowering Therapies (N = 2009)</th>
<th>Placebo (N = 2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>3.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Abdominal pain or discomfort*</td>
<td>3.1</td>
<td>2.2</td>
</tr>
<tr>
<td>Anemia</td>
<td>2.8</td>
<td>1.9</td>
</tr>
<tr>
<td>Back pain</td>
<td>3.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>3.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Carpal tunnel syndrome</td>
<td>3.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2.8</td>
<td>1.9</td>
</tr>
<tr>
<td>Elevated liver enzymes*</td>
<td>2.1</td>
<td>0.8</td>
</tr>
<tr>
<td>Headache</td>
<td>2.8</td>
<td>1.9</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>3.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Hypersensitivity and blood uric acid increased</td>
<td>3.6</td>
<td>2.3</td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>3.3</td>
<td>2.2</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>3.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Rash</td>
<td>3.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>4.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>4.5</td>
<td>4.0</td>
</tr>
<tr>
<td>Elevation of liver enzymes</td>
<td>2.1</td>
<td>0.8</td>
</tr>
</tbody>
</table>

*Hypersensitivity includes hypersensitivity and blood uric acid increased.
*Abdominal pain or discomfort includes abdominal pain, abdominal pain upper, abdominal pain lower, and abdominal pain/discomfort.
*Elevated liver enzymes includes AST increased, ALT increased, hepatic enzyme increased, and liver function test increased.

Tendon Rupture: NEXLETOL was associated with an increased risk of tendon rupture, occurring in 0.5% of NEXLETOL-treated patients versus 0.1% of placebo-treated patients. Gout: NEXLETOL was associated with an increased risk of gout flare, occurring in 7% of NEXLETOL-treated patients versus 1% of placebo-treated patients. The clinical significance is unknown.

Recommended dose: Experimental data suggest that a diet with saturated fat content of 10% of total energy is associated with a lower risk of atherosclerotic cardiovascular disease. In particular, cholesterol-lowering diets that are high in monounsaturated and polyunsaturated fats and low in saturated fats appear to reduce the risk of coronary heart disease.

NEXLETOL is usually given once daily with or without food. It is important to take NEXLETOL at the same time each day to maintain consistent levels of bempedoic acid in the blood.

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Pediatric Use: The safety and effectiveness of NEXLETOL have not been established in pediatric patients.

Geriatric Use: Of the 2009 patients in clinical trials of NEXLETOL, 753 (38%) were 65 years and older, while 478 (24%) were 75 years and older. No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences that would be expected to affect the use in elderly patients. However, greater sensitivity of some older individuals cannot be ruled out.

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Pharmacy Schools Prepare Students for Specific Population Challenges

By Aine Cryts

A pharmacy desert is defined as an area where limited access to pharmacies is acute. A 2014 study in *Health Affairs* found that segregated black and Hispanic communities in Chicago, Illinois are more likely to be host to pharmacy deserts and that 1 million people in the city were living in these pharmacy deserts. Fifty-three percent of those individuals were living in segregated black communities.

In addition to dispensing prescription medications, local pharmacies have a role to play in the sale of OTC products and, increasingly, the provision of diagnostic, preventive, and urgent-care services, wrote the study coauthors. Pharmacists, in particular those practicing in retail environments, are often the most accessible health care professionals, said Sean Nordt, MD, PharmD, associate dean of academic affairs, chief medical officer, and professor of pharmacy at Chapman University School of Pharmacy in Irvine, California. Whereas a patient needs to register at the hospital to see a physician, all they need to do is walk into their local pharmacy to ask questions, he explained.

That’s why lack of access to pharmacies can have a detrimental effect on patients, in particular those with chronic conditions, said Stephanie Kiser, PharmD, clinical assistant professor at the University of North Carolina Eshelman School of Pharmacy in Chapel Hill. A pharmacist for more than 25 years, Kiser grew up in a rural area and witnessed firsthand that accessing care often requires driving far distances.

She cited the example of a patient who needs to be monitored in person twice weekly until their body adjusts to an anticoagulant. Although that involves 4 inconvenient 10-minute car rides for someone in a suburban area, it could require a 90-minute drive twice a week for the person who lives in a rural area, she explained.

According to a 2018 study in *Rural Policy Brief*, 16.1% of independently owned rural pharmacies closed between 2003 and 2018. A 2019 study in *JAMA Network Open* found that pharmacy closures “are associated with persistent, clinically significant declines in adherence to cardiovascular medications among older adults in the United States.”

**Engaging Homeless Populations in Accessing Care**

Skid Row is a 53-block area east of downtown Los Angeles, California where approximately 2700 members of the homeless community live.

To encourage members of Skid Row’s homeless population to seek health care, Jemal Hussein, a PharmD student at Keck Graduate Institute’s School of Pharmacy and Health Sciences in Claremont, partners with students at local health sciences graduate schools, such as the University of California, Los Angeles, School of Dentistry and the Marshall B. Ketchum University School of Physician Assistant Studies in Fullerton.

One tangible impact of their work is the care kit, which includes items such as a toothbrush, toothpaste, sanitary pads, articles of clothing (such as a T-shirt, socks, or a sweater), and a handwritten note from one of the student volunteers. The idea behind the note is to tell the person that “you’re loved and thought about,” said Hussein, who leads the graduate school’s Community, Advocacy, Resources, Education, organization. Volunteers use the interaction to spark a conversation, which can help get members of the homeless population access to the medication, dental, and health care services they need, he explained.

**Connecting to Patients Through Shared Language and Culture**

Samantha Garcia, who is also pursuing a PharmD degree at Keck Graduate Institute, said that speaking the same language as the person you’re treating makes a difference. In particular, patients need to understand that taking their blood pressure medication can keep them out of the hospital, she noted. “It’s difficult if your pharmacist or doctor can’t speak your language and you need to take this medication to prevent [you from] having a stroke or a heart attack,” said Garcia.

According to Garcia, her proficiency...
in Tagalog, the primary language spoken in the Philippines, came in handy last semester at a clinic held for members of the homeless community in nearby Pomona. Services at the clinic included blood pressure checks and education about the signs and symptoms of stroke. As soon as her patient heard her speak in Tagalog, she “perked up,” Garcia said, despite the fact that she was counseling the patient against eating fried pig, a popular Filipino dish, which isn’t good for her health.

It’s important for providers to make that connection with patients and close that gap in a culturally aware manner, said Garcia, who leads the Student National Pharmaceutical Association chapter at the graduate school.

**Diagnosing and Treating Asthma in Children**

More than 22% of schoolchildren in Pittsburgh, Pennsylvania, have asthma, according to a *Journal of Allergy and Clinical Immunology* study published in 2018. That’s more than double the state’s asthma prevalence rate of 10.2% among children and significantly higher than 7.5% for children across the country.

Patients with persistent asthma need access to their daily medications for the condition to be well controlled, explained Jennifer Padden Elliott, PharmD, associate professor at Duquesne University’s School of Pharmacy in Pittsburgh. If their asthma isn’t well controlled, children end up in the emergency room and miss school days, she added.

In 2014, Elliott developed a community-based screening model to diagnose asthma in children and connect them with the care they need. The free service is available in schools throughout Allegheny County, which is home to Duquesne University. The screening model starts with a health questionnaire sent to parents at the start of the school year. Students in Duquesne University’s pharmacy program help tabulate the results and reach out to parents.

In addition, Elliott launched school-based asthma clinics in partnership with federally qualified health centers in the surrounding neighborhoods in 2017. For clinical pharmacists from Duquesne University’s pharmacy, schoolwork takes place at the asthma clinics, where the condition is managed during the school day and medication changes and other updates are communicated to the student’s primary care physician. For example, students can have their lung function assessed using a spirometer at the asthma clinics.

Students in Duquesne University’s pharmacy program can participate in rotations with the asthma clinics, said Elliott. They shadow pharmacists who staff the program and help counsel children and their families on topics such as inhaler techniques and adherence with treatment plans.

**Exposing Pharmacy Students to Urban and Rural Experiences**

Patients struggle to manage chronic conditions such as diabetes in rural and urban areas, explained Estela Lajthia, PharmD, clinical assistant professor at Howard University in Washington, DC. The same challenges associated with drug prices and lack of access to preventive care also plague people in rural and urban settings, she said.

To expose its students to the experience of serving as pharmacists in a rural environment, Howard University has partnered with the University of Wyoming School of Pharmacy in Laramie on an exchange program, with 4 students from both schools traveling to the other school since fall 2018.

Students from Wyoming School of Pharmacy learn about health care systems in inner-city Washington, DC, and meet congressional leaders, and Howard University students are exposed to critical-access hospitals and health care systems in rural settings, said Lajthia, an ambulatory care pharmacist.

Lack of convenient access to health care services and increasing closures of independent pharmacies contribute to gaps in patient care in both rural and urban settings. Exposing pharmacy students to these work experiences in pharmacy desert neighborhoods can prepare the next generation of pharmacists to close these gaps.
The Pharmacist’s Role in Heart Health

By Frieda Wiley, PharmD

Heart disease is so common among Americans that it claims 1 life every 37 seconds. That number accounts for approximately 647,000 deaths annually, according to the CDC. As health care providers often serving on the front lines, pharmacists have potentially underused opportunities to help keep patients’ tickers in tip-top shape.

The underutilization of pharmacists in wellness and disease-state management may come from the lack of recognition they receive for the value they add to the patient care equation, according to Andrew M. Freeman, MD, FACC, FACP, a cardiologist, cochair of the Nutrition & Lifestyle Work Group of the American College of Cardiology, and director of cardiovascular prevention and wellness at National Jewish Health in Denver, Colorado.

“For a long time, pharmacists have been very much underappreciated in day-to-day care,” he told Drug Topics. “From a cardiovascular perspective on the inpatient side, they are an essential part of the team to make suggestions for things we doctors may not readily know offhand.” For example, Freeman appreciates having pharmacists give recommendations on tailoring drug therapy based on their assessments of electrolytes, allergies, and various interactions such as drug-drug, drug-nutrient, and drug-herbal interactions.

However, the diverse ways in which pharmacists can alter the patient experience transcend the support they offer physicians in drug therapy. Twenty percent of hospital readmissions are linked to inefficiencies in the coordination of care. These challenges highlight additional gaps in the health care systems that pharmacists can help fill.

“Pharmacists have become essential to preventing readmissions because they provide education to patients at discharge,” Freeman said. “They help keep them from returning to the hospital and out of the clinic.”

Patients with recent cardiovascular events may require education on as many as 4 to 6 new medications that were started during hospitalization, according to Alison M. Walton, PharmD, BCPS, associate professor of pharmacy practice, ambulatory care clinical pharmacy specialist, and director of Healthy Horizons at Butler University College of Pharmacy and Health Sciences in Indianapolis, Indiana.

Patient education has also become extremely important in managing cardiological conditions such as hyperlipidemia and hypertension. Topics include healthy lifestyle habits as well as disease-state and drug information. Helping patients understand the importance of medication adherence and solving adherence-related problems is another element in the patient education spectrum.

“Since patients can’t feel their cholesterol or blood pressure levels, it’s difficult for [them] to realize the impact medications have on their heart numbers,” said Walton.

For that reason, educating patients on

“The role of the pharmacist is to make sure patients understand their therapies and appropriately utilize their drugs. But sometimes the pharmacist is the link when other providers do not speak to each other.”

ANDREW M. FREEMAN, MD, FACC, FACP.

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their medications is extremely important—especially as they transition through the health care system from different settings.

Additionally, the coronavirus disease 2019 (COVID-19) pandemic has created another much-needed opportunity for pharmacists to provide information to patients with cardiac conditions, especially as having preexisting conditions increases the risk of developing complications. Altered lifestyle habits as a result of the COVID-19 lockdown also pose further risks to such patients. "As a result of COVID-19, our daily routines have significantly changed, and this may impact the lifestyle choices of our patients with disease," said Walton. The COVID-19 crisis has created some conditions that may limit some outdoor physical activities or force some patients to alter their eating habits in a potentially unhealthful way. A more sedentary lifestyle could negatively affect blood pressure and cholesterol. Further, with fresh produce now hard to come by, many patients may increase their consumption of frozen or canned products; as a result, they may also inadvertently increase their sodium intake.

"Throughout their career, a pharmacist may have multiple roles in the prevention and management of cardiovascular disease," said Walton. Pharmacists’ frequent interactions with patients create recurring opportunities to help optimize patient care. One illustration of a productive interaction is a pharmacist initiating a referral after an encounter in which a patient describes signs and symptoms of cardiovascular disease.

From Freeman’s perspective, one of the most critical ways in which pharmacists enhance patient care is by serving as an intermediary or conduit of sorts. “The role of the pharmacist is to make sure patients understand their therapies and appropriately utilize their drugs,” he said. “But sometimes the pharmacist is the link when other providers don’t speak to each other.”

As health care continues its massive overhaul, the links, or bridges, that pharmacists build with their unique blend of skills should only continue to grow.

For references, visit drugtopics.com.
Career

The Carbon Footprint in the Room: Going Green in Pharmacy

By Gabrielle Ientile, Assistant Editor

According to the International Pharmaceutical Federation, pharmacists are responsible for minimizing the effect their practice has on the environment through changes in “prescribing, dispensing, pharmaceutical care, and disposal of unused medicines, as well as waste discharge into the environment.”

That’s no small order to fill. The global health care climate footprint is equivalent to 4.4% of global net emissions, with the US health sector making the highest contributions. Sustainable development takes time, resources, and a consensus that the environment is worth all this work. As the global landscape widens and resources are strained, pharmacists must now figure out what it means to be sustainable in the industry and how to get involved in these initiatives.

Dorie Apollonio, PhD, professor at University of California, San Francisco (UCSF) School of Pharmacy, whose focus is on translating research into policy, has served as a member of UCSF’s Chancellor’s Advisory Committee on Sustainability (CACS) since its inception in 2008. She outlined the most effective ways for pharmacists to start making sustainability a priority in their practice in an email to Drug Topics.

“The three r’s—reduce, reuse, recycle—are still a great approach to developing a more sustainable pharmacy,” Apollonio said. “Most pharmacies are equipped with e-prescribing, which can help reduce the amount of paper use from faxed prescriptions. Pharmacies can also incorporate recycling of non-HIPAA documents as well as recycling of medication stock bottles. Before recycling medication bottles, pharmacies should check with their local recycling services to make sure they are accepted.”

“Patients interested in recycling medication bottles should also refer to their local recycling regulations,” Apollonio added. “Several pharmacies now offer medication take-back services, where patients can safely dispose of unused/unneeded medications. Most pharmacies avoid reusing medication vials due to sanitary concerns; however, some individuals are working on creating reusable medication vials for the public.”

Although some recommendations offer small-scale efforts, others address the institutional nature of sustainability within the health care system. “Some pharmacies may also consider procuring generic drugs from companies that uphold sustainable principles to incentivize pharmaceutical companies to continue these efforts,” Apollonio said.

Katherine Gruenberg, PharmD, assistant professor at UCSF School of Pharmacy and a pharmacist specializing in infectious diseases, explained some of the environmental problems surrounding anesthetic medications in particular. “We’re trying to raise awareness for both anesthesiologists and pharmacists about the potential pollution and trying to reduce and refine how we practice…Instead of drawing up 2 propofol syringes just in case, but not opened, “ she said. “Just things like that. And also, the use of local anesthetics…really helped us.”

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According to Gruenberg, prior to their approval in the United States, medications must undergo an environmental risk assessment via the FDA.

“Some compounds may present a greater direct risk to aquatic, terrestrial, or atmospheric environments on the basis of their chemical properties. By developing compounds that degrade more readily, their environmental impact can sometimes be mitigated. In direct environmental effects can also be reduced through use of less toxic reagents and development of more efficient processes that require fewer synthetic steps,” said Gruenberg.

Vivian Ip, MBChB, one of the founders of the American Society of Regional Anesthesia and Pain Medicine’s Green Anesthesia Special Interest Group (GASIG), explained some of the environmental problems surrounding anesthetic medications in particular. “We’re trying to raise awareness for both anesthesiologists and pharmacists about the potential pollution and trying to reduce and refine how we practice…Instead of drawing up 2 propofol syringes just in case you don’t have enough, there are alternatives, like drawing up 1 and then maybe have another ampule just in case, but not opened,” she said. “Just things like that. And also, the use of local anesthetics…really helped us. Firstly, you’re reducing the amount of narcotics around and, hence, narcotics wastage…[Secondly, it’s important] to actually avoid using sevoflurane and propofol, for example, which pollutes...
“We are a huge part of the problem in terms of bringing sickness to the planet and ultimately to the people and basically all organisms that live on it, which is really contradictory to what we all set out to do, right? It is our mandate to help anybody whom we can help, not only that to people but to all living organisms and to the planet as a whole. And we are falling direly short of that goal right now,” Ozelsel said.

GASIG’s passion for sustainability has brought about numerous successes so far.

“A lot of places are going to get rid of desflurane in the future, which was our first goal to accomplish,” GASIG founder Rakesh Sondekoppam, MD, University of Alberta, said. “And I think lots of places are going that route. Second thing, the whole reason why we started the GASIG is to promote regional anesthesia as the green choice. And I think that’s very supportive to the whole initiative. I think it’s gaining traction.”

The CACS has also successfully instituted sustainability efforts at the UCSF campus. “The CACS has made a major effort to reduce waste, and UCSF now diverts 78% of its waste to recycling and compost, an increase from 44% in 2008,” Apollonio explained. “This has involved efforts across all campus divisions to reduce single-use items, including the hospital pharmacies. The UCSF Parnassus campus also has a Walgreens store onsite, which has a safe medication disposal bin.”

Some regions of the United States have been particularly proactive in supporting sustainable pharmacy growth at the legislative level. “At the state and local level there is increasing advocacy for safe medication-disposal programs, often described as ‘take-back programs.’ Historically, drug take-back events were rare, once a year, and voluntary. The City and County of San Francisco enacted a Safe Drug Disposal Ordinance in 2015,” Apollonio said. “More recently, multiple states have passed legislation requiring drug companies to organize and fund these programs, with varying degrees of implementation, and in 2020, New Jersey passed legislation requiring pharmacists to provide safe medication-disposal methods at no cost to consumers.”

According to Apollonio, although these programs are primarily focused on reducing opioid abuse and overdoses, safe medication disposal also reduces the likelihood that drugs will enter the environment. For example, prescription drugs containing estrogen that enter the watersheds have caused cancers and other disorders in fish. “On the federal level, the US [Environmental Protection Agency] has focused on management of pharmaceutical hazardous waste, with guidances issued in 2008 and 2019,” Apollonio said. “The 2019 rule bans sewering but also allowed health care facilities to accumulate larger quantities of hazardous waste onsite without following associated regulations and redefined nicotine-containing products (eg, patches) as ‘nonhazardous,’ increasing the risk that these products will enter the environment.”

Taking on sustainability can be overwhelming, and sometimes it can feel that 1 person going green won’t change anything. GASIG’s experts said finding like-minded people to take it on together makes a big difference.

“You seem like you’re taking 1 step forward while somebody else is trying to pull you 2 steps back,” Ozelsel said. “It’s something that requires a lot of passion [and] enthusiasm, and we’re very happy that we’re finding people that have like-minded interests...and that we are gathering people to speak with a louder voice cumulatively.”
Digital health technology is transforming every aspect of pharmacy practice, whether it deploys robotics to fill prescriptions, uses analytics to track medication data, or offers access to digital therapy. Pharmacists in both the hospital and retail settings are using recently developed technology to prevent adverse drug effects, monitor the use of antibiotics, modify unhealthy behavior, and promote medication adherence.

Not only can technology make a pharmacist’s day more efficient by automating repetitive tasks, but new digital health products are providing more insight into data and the opportunity for real-time patient interaction.

Monitoring Medication
One type of digital health technology that helps pharmacists monitor adherence is an at-home medication dispenser that lets them know, in real time, whether the patient is actually taking the medication.

Developed by Catalyst Healthcare and a feature of the Pack4U connected care system, spencer is a dispenser and monitor that not only reminds patients when it’s time to take medication but offers them a way to communicate concerns remotely with a pharmacist, who can then troubleshoot any required solutions. The integrated system offers several advantages in treating high-risk patients, who are often on multiple medications.

"The pharmacy in our model is usually responsible for delivering a specially packaged cartridge to the patient, and then at the patient level, we have the device that sits on the patient’s countertop, called spencer," said Shane Bishop, founder and CEO of Catalyst Healthcare and Pack4U. "The patient can slip the cartridge into the device. We check and
Technology Innovations

make sure the right patient gets the right cartridge for the right device, and then the pharmacy is connected in real time with the device on the countertop."

When the patient takes out the medication, a question may pop up on the screen, such as “How are you?” Or the question can be customized to the particular medication or condition.

Prescriptions are packed centrally, then shipped back to pharmacies. Each step of the process is tracked, including who sent the order, where the order is, who received it, and even expiry dates. Spencer also notes adherence problems, while collecting data on medication use, that can prove valuable to research.

“You get the responses back in real time,” said Bishop. “So now you can turn that data into being proactive for that patient and even triage that information for clinicians and physicians, as well as making pharmacy very relevant in the care of the patient, because pharmacists can get access to data faster than anyone else involved in care.”

Telehealth solutions have been invaluable during the quarantine prompted by the coronavirus disease 2019 (COVID-19) epidemic, providing a link to housebound patients who require ongoing care for chronic conditions.

“Our adherence rates run at 98%, and that’s actual medication in the patient’s hand at the time they are supposed to take it,” said Bishop. “It keeps the patient safe at home and lowers the total cost of care.”

Although the system primarily works with retail pharmacies, hospitals can discharge patients with the device so a pharmacist network can remotely monitor the patient. One advantage to this technology, according to Bishop, is that pharmacists have more time to focus on patients.

“I believe there is a lot of capacity in pharmacy to do much more than they’ve been tasked with,” he said.

**Digiceuticals and Behavior Modification**

When it comes to behavior modification therapy, there’s now an app for that—an app that requires a prescription.

Technology-based therapy, known as digiceuticals, uses FDA-approved apps on smartphones, tablets, and other mobile devices to gather data and provide patients with real-time guidance.

Digiceuticals can be used as monotherapy or in addition to medication. Pear Therapeutics created reSET, which can be used as an adjunct to a contingency management system, to treat some forms of substance abuse. The company’s reSET-O targets opioid addiction as part of a treatment plan that also includes medication. Somryst, the company’s newest product, provides cognitive behavioral therapy for chronic insomnia.

“As these products become more and more sophisticated in relation to [their] use in conjunction with other medications, the role of the pharmacist is going to be how to use them in terms of the patient’s overall medication,” said Yuri Maricich, MD, MBA, chief medical officer and head of development at Pear Therapeutics.

A code is required to access these apps. Before dispensing the code, pharmacists need to review the patient’s profile. “With all of these [apps], the way they are dispensed is [by] the prescription [being] sent to a specialty pharmacy where a pharmacist reviews the information,” said Maricich. “A pharmacist reviews every script. If everything looks copacetic, they actually dispense and fill, providing patients with a prescription access code. The patient then goes to Google Play or the Apple apps store. They download the software, input their prescription access code from the pharmacy, and get access to that treatment for the prescription duration. If the patient wants a renewal or a refill, that can be done.”

According to Maricich, the difference between digiceuticals and biologic medicine will eventually fade away until it will all simply be described as medicine.

“This is something that can be prescribed through a telemedicine visit and filled and used without ever having to physically go to a clinic,” said Maricich. “In an era where we’re moving into virtual care, it will fit more and more into models outside traditional brick-and-mortar care delivery.”

**Preventing Adverse Effects**

According to the CDC, between 2013 and 2016, almost half of all Americans took at least 1 prescription drug in the prior 30 days, 24% took 3 or more, and 12.6% took 5 or more, raising the risk for adverse effects (AEs).1 To assess risks in patients taking multiple medications, the Tabula Rasa HealthCare (TRHC) MedWise Risk Score (MRS) employs technology that identifies and aggregates markers of AEs.

“These risk factors are considered in an algorithmic approach, designed using millions of patients’ data, which creates the MedWise Risk Score,” said Robert L. Alesiani, PharmD, chief pharmacotherapy officer at TRHC. “Each patient has a dynamic risk score that changes with modification in medication therapy. We can pinpoint and act upon medication risks identified using the risk score. We also can predicate the impact of MRS, including changes in total medical spend. The MedWise system is built by pharmacists for pharmacists, incorporating the array of science we learned in pharmacy school—pharmacodynamics, pharmacokinetics, pharmacogenomics, pharmacology, and chronopharmacology.”

Rather than depend on a series of 1-to-1 drug interactions for each patient’s drug profile, the system performs a simultaneous aggregate drug
interaction check that can help identify high-risk and unsafe medication regimens, overprescribing, inappropriate prescribing, overutilization, improper or suboptimal administration schedules, and drug-genie and drug-drug gene interactions. By reducing the AE risk, the analysis also lowers the medical costs associated with treating potential health problems.

“Without a complete medication reconciliation, profile omissions represent interactions missed, increased risks of oversedation, symptoms of delirium [and] confusion, impaired gait leading to falls with injury, irregular heart rates, and, at worst, sudden death,” said Ale siani. “When a patient is taking an enzyme-inhibiting medication, it can affect so many other medications on the profile. If we don’t know about that drug, our recommendations could be useless.”

Technology can help pharmacists stay up-to-date on interactions. “When patients are on 2, 3, or more medications that are metabolized through the same drug-metabolizing enzyme, these drugs compete for the same drug-metabolizing enzyme, these drugs compete for the metabolism,” said Ale siani. “Pharmacists learned all about this in school, but there’s no way to memorize metabolic pathways for every drug on the market and then efficiently apply that knowledge in daily pharmacy practice.”

**Antibiotic Stewardship in Real Time**

According to the CDC’s 2019 AR Threats Report, antibiotic-resistant bacteria and fungi cause more than 2.8 million infections and 35,000 deaths in the United States each year. To track and better steward antibiotic use, Becton, Dickinson and Company (BD) integrated new analytics into the company’s connected medication management platform. These analytics provide near real-time alerts when an inappropriate and potentially ineffective antibiotic has been prescribed.

“You have all these players-physicians, pharmacists, and nurses—trying to make sure that the right medication gets to the right patient at the right time at the right dose,” said Clint Pridgen, platform leader, MedMined Surveillance Services at BD. “It seems like that would be a pretty simple process, but every player has a different piece of information and because everyone is moving so fast, that information doesn’t always translate from person to person to person.”

Members of a health care team can receive alerts on lab results and changes in a patient’s condition, which may prompt a timely reassessment of the medication regimen. The results from the latest lab tests might, for example, suggest that a drug that was appropriate from an antimicrobial stewardship perspective when it was prescribed may no longer be the best medication.

Health systems have more data than ever before. Although useful, data can take time to process. A pharmacist who is responsible for 30 to 40 patients each day may receive a constant influx of information, which needs to be organized and prioritized. The COVID-19 pandemic clearly illustrates the need for the efficient collection and organization of data.

“Blending in technology that closes in the gaps in visibility enables you to identify patients that are infected or identify resistant organisms or to identify trends that allow health systems to get in front of pandemics and epidemics as quickly as possible.”

CLINT PRIDGEN, PLATFORM LEADER, MEDMINED SURVEILLANCE SERVICES AT BECTON, DICKINSON AND COMPANY

**For references, visit drugtopics.com**
Never before have so many brilliant minds, machines, and groups come together so quickly in an attempt to develop a vaccine. The first human trial involving a vaccine product against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the novel coronavirus disease 2019 (COVID-19), began in March in Seattle, Washington. However, some experts in the field say creating unrealistic expectations may be harmful and warn that maintaining standard protocols during the pandemic is essential.

The genetic sequence of SARS-CoV-2 became available online in February. Subsequently, investigators have been able to use this information to find the protein that is critical for the virus to be able to infect humans. The hope is to use a portion of that protein to create a vaccine that will generate an antibody response to prevent the virus from infecting human cells. Some investigators are working on DNA-based vaccines that contain genes that produce the virus’ protein, whereas others are looking at vaccines that include a portion of the actual protein.

“We have never known as much as we do today [about] how to make vaccines. So if there is any bright spot to the pandemic, it is that the scientific world has many tools at hand to make an effective vaccine,” said William A. Petri, MD, PhD, a professor of medicine and vice chair for research in the Department of Medicine at the University of Virginia School of Medicine in Charlottesville. “I hope that COVID-19 will transform medicine by strengthening public support of science, public health, and medicine, and by teaching us that regardless of race, color, ethnicity, or nationality, we are all in this together.”

Petri is working with colleagues at the Infectious Disease Research Institute in Seattle to make a spike glycoprotein vaccine using novel toll-like receptor (TLR) adjuvants. Essentially they are hoping to use COVID-19’s spiked shape against the disease. His group’s vaccine is one of approximately 50 vaccines currently in various stages of development. What will take significant time is that scientists may have to study a range of virus strains in a variety of animal models before any vaccine product could even make it to a phase 3 level of testing.

At The Johns Hopkins Hospital in Baltimore, Maryland, vaccines with different approaches are under development, and scientists have been testing several avenues of crippling COVID-19 in animal studies. The speed of the testing has been incredible,” said Tzyy-Chou “TC” Wu, MD, PhD, MPH, director of the Gynecologic Pathology Division at Johns Hopkins Medicine. He studied the SARS virus in 2002 and 2003 and is drawing on that experience to come up with a safe and effective vaccine.

On March 16 in Seattle, Kaiser Permanente Washington Health Research Institute’s Vaccine and Treatment Evaluation Unit launched a trial of the mRNA-1273 investigational vaccine. This experimental vaccine product is produced by Moderna, Inc, and the trial is expected to take 14 months. It involves 45 healthy individuals, aged 18 to 55 years, from the Seattle region. The product includes messenger RNA for the viral spike (S) protein. It does not include any form of live virus, and the trial will not expose participants to the virus.

The vaccine involves a series of 4 injections, and the investigators are testing safety and antibody production. It is an mRNA vaccine encoding for a prefusion stabilized form of the S protein, which was selected by Moderna in collaboration with the National Institute of Allergy and Infectious Diseases. The S protein complex is necessary for membrane fusion and host cell infection and has been the target of vaccines against the coronaviruses responsible for Middle
East respiratory syndrome (MERS) and SARS virus.

Coronaviruses are a family of viruses that include MERS and SARS. They are transmitted between animals and humans and can evolve into strains not previously identified. Wu and his colleagues have found that COVID-19 is continuing to evolve; consequently, it may be necessary to ensure that the portion of the protein and its genetic sequence will remain effective should the virus mutate or change.

“Several vaccines are advancing into clinical trials, [and] we are working to include our vaccine,” said Peter Jay Hotez, MD, PhD, dean for the National School of Tropical Medicine at Baylor College of Medicine in Houston, Texas. He said it is possible that a vaccine will become available and ultimately delivered in the pharmacy. “[As] this may be an adult vaccine, we think it’s likely that in time it could be administered by pharmacists,” Hotez told Drug Topics.

On March 30, investigators at the University of Alabama at Birmingham announced the launch of their collaboration with Alimmune, Inc, for preclinical testing of a potential vaccine to prevent COVID-19 disease.3 The experimental product, named AdCOVID, would be a single-dose vaccine delivered by an intranasal spray. The investigators are examining immune responses to the vaccine in mice and are hoping to launch a phase 1 human safety and immunogenicity trial in patients in September.

What We Learned From the Past

Henry L. Miller, MD, a senior fellow at the Pacific Research Institute in San Francisco, California, was the FDA medical reviewer and head of the team that approved the first biopharmaceutical recombinant human insulin (Humulin) in 1982. He said that never before has there been such a worldwide effort to develop a safe and effective vaccine. “The good news is that the approaches are very different and varied, improving the chances that 1 or more will be successful,” Miller told Drug Topics® in an email.

However, he said the challenge is the nature of the vaccine products under way, all of which so far involve novel technologies. This will make regulators more conservative in their evaluation and approval. “The facile prediction of 12 to 18 months is a pipe dream, off by at least a factor of 2, probably more,” said Miller. Getting to a phase 1 level is not a problem; however, he stated that the FDA had a significant role in a debacle surrounding a vaccine to prevent swine flu virus infections almost a half-century ago. “Of the 45 million people vaccinated against the swine flu in 1976, 450 developed a serious adverse reaction, the rare, paralytic Guillain-Barré syndrome. What made the situation even more unfortunate for regulators is that the predicted epidemic never materialized, so the vaccine wasn’t needed,” said Miller.

It is for this reason that the FDAs regulation of vaccines is especially conservative, he continued, and the bar has remained high for the approval of vaccines administered to millions of healthy people. According to Miller, the first rotavirus vaccine, RotaTeq, was tested in 72,000 healthy infants and the first human papillomavirus vaccine, Gardasil, was tested in more than 24,000 people.

Immunologist Adrian Liston, PhD, a senior group leader at the Babraham Institute and head of the VIB Translational Immunology Laboratory in Cambridge, England, disagrees with Miller. He said that how soon a vaccine becomes available will be dictated by how many thousands of deaths occur in the next 6 months. Liston told Drug Topics® that he expects a vaccine to be rolled out within the next 12 months and it may come with more risks than previous vaccines. He said a vaccine that is only 50% efficacious and causes minor adverse effects in up to 10% of people may be acceptable.

“It will skip a lot of the normal safety and efficacy steps, and it will likely be a much poorer vaccine than we are used to seeing, but it will likely have utility. Then, toward the end of 2021, I would expect to see the rollout of better vaccines, with higher levels of efficacy and fewer adverse effects. At some point in the future, every child will likely be given a vaccine for COVID-19 as part of their routine vaccination schedule, but that is much more likely to be a third- or fourth-generation vaccine, with the optimal properties that we expect,” said Liston.

David J. Prelutsky, MD, medical director and founder of Southampton Healthcare and an associate professor of clinical medicine at Washington University School of Medicine in St Louis, Missouri, said there are many similarities between the spread of HIV and SARS-CoV-2. He highly suspects that a vaccine will be approved within the next 6 to 12 months. “I believe, [as] with HIV, therapeutic agents will be the answer and not a vaccine in the immediate future,” Prelutsky said. “There may be a vaccine, but that will take longer to develop.”

For references, visit drugtopics.com

Vaccines / Flurry of COVID-19 Vaccine Studies Underway

“As] this may be an adult vaccine, we think it’s likely that in time it could be administered by pharmacists.”

PETER JAY HOTEZ, MD, PHD
Investigational Drugs in the Pipeline for COVID-19

By Jennifer Gershman, PharmD, CPh

Investigators are evaluating a variety of medications for the novel coronavirus disease 2019 (COVID-19), and the possible treatment landscape is rapidly evolving.

There are no FDA-approved medications for the treatment of COVID-19. Currently, medical management consists of infection prevention and supportive care, which includes supplemental oxygen and mechanical ventilator support when indicated.1 At least 181 clinical trials were being conducted as of April 14, 2020, comprising studies at the recruiting stage and those that have already begun.2

**COVID-19 Investigational Treatment Options**

**REMDESIVIR**

Remdesivir is an intravenous (IV) drug with broad antiviral activity (eg, severe acute respiratory syndrome [SARS] virus and Middle East respiratory syndrome) that has been used for the treatment of Ebola virus, and it works by inhibiting viral replication through premature termination of RNA transcription.3,4 Additionally, remdesivir appears to have a favorable safety profile based on its having been used to treat approximately 500 individuals, including healthy volunteers and those with acute Ebola virus infection.3 Remdesivir is being studied by Gilead Sciences for the treatment of COVID-19, and evidence suggests that it is currently one of the most promising investigational drugs.5

Results of a cohort study were published in the *New England Journal of Medicine* on April 10, examining compassionate use of remdesivir in 61 patients hospitalized with COVID-19 with an oxygen saturation of 94% or less while breathing ambient air or who required oxygen support.4 Patients received a 10-day treatment of IV remdesivir 200 mg on day 1 followed by 100 mg for the remaining 9 days of therapy. Fifty-three patients had data analyzed (7 lacked posttreatment data, 1 had dosing error), and clinical improvement was seen in 68% of patients.4 A total of 32 patients (60%) reported adverse events (AEs) during follow-up.4 The most common AEs were increased hepatic enzymes, diarrhea, rash, renal impairment, and hypotension. Twelve patients (23%) experienced serious AEs, including multiple organ dysfunction syndrome, septic shock, acute kidney injury, and hypotension, with most occurring in those receiving invasive ventilation.4 The results are promising; however, more robust studies are needed to determine the safety and efficacy of remdesivir for patients with COVID-19. Study limitations included the drug not being randomized and lacking a control, missing data, and a short follow-up duration.4

There are currently 2 phase 3 randomized clinical trials, known as the SIMPLE studies, for patients with severe COVID-19 symptoms (NCT04292899) and for those with moderate symptoms (NCT04292730).5,6 Gilead released topline results from the SIMPLE trial studying patients with severe COVID-19, which demonstrated similar improvement with the 5- and 10-day treatment regimens of remdesivir.5 Time to improvement for 50% of study participants was 10 days in the 5-day treatment group, and more than half of patients in both groups were discharged from the hospital by 14 days.5 Results are expected by May 2020 for the study evaluating patients with moderate COVID-19.5 Gilead is currently working on transitioning to expanded access of remdesivir for patients with severe symptoms and will collect and analyze treatment data.6

**HYDROXYCHLOROQUINE, CHLOROQUINE, AND AZITHROMYCIN**

The FDA recently issued an emergency use authorization (EUA) for the antimalarial drugs chloroquine and hydroxychloroquine (Plaquenil) for the treatment of hospitalized adult and adolescent patients with COVID-19 who are unable to participate in a clinical trial and who weigh 50 kg or more. These medications have immunomodulatory activity that could contribute to an anti-inflammatory response, which is the theoretical mechanism of action for the proposed treatment of COVID-19.7 The dosage of hydroxychloroquine recommended by the EUA is 800 mg on the first day of treatment followed by 400 mg daily for 4 to 7 days of total therapy, based on clinical evaluation.9 Chloroquine’s EUA recommends 1 g
on day 1 followed by 500 mg daily for 4 to 7 days of total treatment, based on clinical evaluation. However, there is much controversy surrounding these drugs, as their safety and efficacy for the treatment of COVID-19 have not been established. Limited evidence suggests that these medications may have clinical benefits in patients with COVID-19.

Hydroxychloroquine with azithromycin was examined in observational and nonrandomized studies in France for the treatment of COVID-19, but data were limited, as many individuals were considered to be low risk and only a small number of patients were included. Azithromycin has immunomodulatory and anti-inflammatory properties, but there are currently insufficient data for its adjunctive use in the management of COVID-19. Both hydroxychloroquine and azithromycin are associated with QT prolongation. A jointly published guidance was released April 8 by the American Heart Association, the American College of Cardiology, and the Heart Rhythm Society regarding possible serious health risks associated with hydroxychloroquine and azithromycin use. Recommendations include QT interval monitoring, withholding hydroxychloroquine and azithromycin in patients with baseline QT prolongation or known congenital long QT syndrome, correcting hypokalemia and hypomagnesemia, and avoiding other QTc-prolonging medications.

The safety and efficacy of hydroxychloroquine for the treatment of COVID-19 will be further evaluated in the ORCHID Study by the National Heart, Lung, and Blood Institute. This phase 3 multicenter, placebo-controlled, randomized trial aims to enroll approximately 500 patients and is estimated to have initial results by April 2021. Chloroquine studies are also underway in China and other countries, as there is currently limited evidence regarding the drug’s effectiveness for COVID-19. One randomized phase 2b clinical trial compared high-dose chloroquine (600 mg twice daily for 10 days) with low-dose chloroquine (450 mg for 5 days, twice daily only on first day) in 81 patients with severe COVID-19 in Brazil. All patients also received azithromycin and ceftriaxone. The fatality rate was 13.5%, with more deaths and QTc prolongation occurring in the high-dose treatment group. The study halted the high-dose treatment arm and results were posted to medRxiv, but the study has not yet been peer reviewed. These results shed light on cardiac AEs potentially being dose dependent.

**TOCILIZUMAB**

Tocilizumab (Actemra), manufactured by Genentech, is a recombinant humanized monoclonal antibody that is an interleukin receptor antagonist, with a proposed mechanism of action that combats cytokine release syndrome symptoms in severe cases of COVID-19. The drug is currently approved to treat various conditions such as rheumatoid arthritis; however, there are limited data demonstrating that tocilizumab shows benefit for severe COVID-19 symptoms and results in fever reduction and a decreased need for supplemental oxygen. As tocilizumab is an immunosuppressive drug, it can increase the risk of serious infections. A phase 3 randomized multicenter study is underway to evaluate the safety and efficacy of tocilizumab in hospitalized patients with severe COVID-19 pneumonia.

Investigators are evaluating other drugs for the treatment of COVID-19 (see Table). For references, visit drugtopics.com

**TABLE. Other COVID-19 Investigational Therapies**

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Manufacturer/research sponsor</th>
<th>Development stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lopinavir and ritonavir (Kaletra)</td>
<td>AbbVie Inc</td>
<td>Mixed evidence on HIV protease inhibitor efficacy; randomized controlled trial in China with hospitalized patients with severe COVID-19 showed no benefit. RECOVERY trial in the UK is underway and will examine lopinavir/ritonavir and other therapies for COVID-19.</td>
</tr>
<tr>
<td>EIDD-2801</td>
<td>Ridgeback Biotherapeutics/ Emory University</td>
<td>Oral drug has shown activity against coronaviruses in animal studies, and the FDA has approved the start of human trials.</td>
</tr>
<tr>
<td>Nitric oxide</td>
<td>Bellerophon Therapeutics</td>
<td>FDA granted emergency expanded access for the nitric oxide delivery system INOpulse to be used for COVID-19 treatment, based on positive results from 3 patients. Bellerophon Therapeutics also submitted an IND application to the FDA to study INOpulse in patients with COVID-19 in a randomized trial of approximately 500 patients.</td>
</tr>
</tbody>
</table>

Read any newspaper and you will be confronted with articles related to the opioid crisis. Whether the news is highlighting death related to overdoses, overprescribing, a medication gray market, or physicians sending patients to pill mills, the issue is that too many opioids are being prescribed, and pharmacists must take on additional roles in the national fight against opioid addiction and death. Several states have implemented new rules related to a pharmacy’s reporting obligations, whereas other states, such as New York, are taking distribution companies to court.

What role do pharmacies play in patient addiction, and what should pharmacists do to prepare themselves if served with a subpoena or faced with an audit? Conscientious record keeping is of utmost importance. Pharmacists, at a minimum, should ask themselves the following when receiving prescription orders:

- How many physicians write prescriptions for the patient, and how many of those prescriptions are for opioids?
- How often does the patient change physicians?
- For what condition is the opioid being prescribed?
- How many refills are ordered, and does the patient seek early refills?
- Are several members of a household receiving prescriptions for controlled substances? If so, does the pharmacy have a relationship with those family members?
- Is the pharmacist aware, or does the pharmacist have a reasonable belief, that the prescription was refused by another pharmacy?
- What percentage of prescriptions being filled by the pharmacy are for controlled substances?
- What percentage of pharmacy customers are filling prescriptions for opioids, and for what period are they being refilled?
- What protocols are in place to prevent drug loss and/or theft?
- When filling prescriptions, are all pharmacists determining whether the prescription is being sought to fulfill a medical purpose and/or is in line with a physician’s prescribing practices?

Pharmacists play an essential role in patient health and they should not be on autopilot. In some instances, pharmacists step into the shoes of patients who cannot advocate for themselves or lack knowledge to ask the right questions. For example, some patients rely on their pharmacists to advise them if multiple medications cannot interact with each other. Many patients cannot remember their medications by both name and dose. This puts physicians at a disadvantage if a patient has providers in multiple hospital systems where records are not shared.

Extrapolating this problem into the opioid equation can lead to unsolvable problems. This is likely the rationale behind the “corresponding responsibility” rule found in 21 CFR §1306.04, “the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

Currently, many lawsuits are focusing on drug distributors like RDC and McKesson, which distribute opioid drugs to pharmacies that in turn dispense those drugs to patients. But from 2017 to the present, several pharmacy owners have been jailed and fined millions of dollars for filling fake prescriptions. For example, in 2019, Pauline Tilton, a licensed pharmacist and owner of Oasis Pharmacy in Victorville, California, was sentenced to 63 months in federal prison for illegally distributing oxycodone by filling hundreds of counterfeit prescriptions. Pharmacists need to train staff on spotting counterfeit prescriptions and with complying with state and federal laws, particularly as they relate to controlled substances.

For reference, visit drugtopics.com.

Can Pharmacists Be Blamed as Coconspirators in the Opioid Crisis? What the law says about pharmacists’ role in the opioid crisis—and how to protect yourself. By Rania V. Sedhom, Sedhom Law Group, PLLC
In the wake of the novel coronavirus disease 2019 (COVID-19) crisis, insulin manufacturers and legislators in some states are stepping in to ensure patients with diabetes are able to afford lifesaving medications.

Eli Lilly has made available nonbranded versions of insulin lispro protamine and insulin lispro injectable suspension 100 U/mL (Humalog Mix75/25 KwikPen) and insulin lispro injection 100 U/mL (Humalog Junior KwikPen) at a 50% lower list price than the branded versions.¹

The nonbranded insulin products are now available for order by US pharmacies, Lilly said. These nonbranded options are identical to the branded versions, with different packaging and a 50% lower list price of $265.20 for a package of 5 KwikPens.¹

In early April, the company introduced its Lilly Insulin Value Program, which allows anyone with commercial insurance and those without insurance to fill their monthly prescription of Lilly insulin for $35.² Several other states followed suit. New York, Maine, Utah, New Mexico, Illinois, Washington, Virginia, and West Virginia have all enacted similar laws (Table).³⁴ A number of other states have proposed comparable legislation, as well.⁵

Even with these steps forward, the American Diabetes Association urges the elimination of all cost sharing for insulin in state-regulated health insurance plans until the COVID-19 crisis passes, as well as continuous access to health care for residents with diabetes who have lost their jobs.⁶

For references, visit drugtopics.com

### TABLE. States With Insulin Co-pay Cap Laws

<table>
<thead>
<tr>
<th>State</th>
<th>Co-pay cap</th>
<th>Date effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>$100 for a 30-day supply</td>
<td>January 1, 2020</td>
</tr>
<tr>
<td>Illinois</td>
<td>$100 for a 30-day supply</td>
<td>January 2021</td>
</tr>
<tr>
<td>Maine</td>
<td>$35 for a 30-day supply</td>
<td>As health plans are renewed or issued on or after January 1, 2021</td>
</tr>
<tr>
<td>New Mexico</td>
<td>$35 for a 30-day supply</td>
<td>As health plans are renewed or issued on or after January 1, 2021</td>
</tr>
<tr>
<td>New York</td>
<td>$100 for a 30-day supply</td>
<td>As health plans are issued or renewed on January 1, 2021</td>
</tr>
<tr>
<td>Utah</td>
<td>$30 for a 30-day supply</td>
<td>January 1, 2021</td>
</tr>
<tr>
<td>Virginia</td>
<td>$50 for a 30-day supply</td>
<td>January 1, 2021</td>
</tr>
<tr>
<td>Washington</td>
<td>$100 for a 30-day supply</td>
<td>January 1, 2021</td>
</tr>
<tr>
<td>West Virginia</td>
<td>$100 for a 30-day supply</td>
<td>January 1, 2021</td>
</tr>
</tbody>
</table>
While a great deal of the country was safe at home, pharmacists, pharmacy technicians, and other pharmacy support staff were on the front lines, taking care of patients amid the chaos of coronavirus disease 2019 (COVID-19).

When polled on social media, pharmacists described personally delivering prescriptions, greatly expanding the delivery radius, donating masks to first responders, and bringing food to nurses at hospitals. Pharmacists also discussed the steps taken to keep the pharmacy as clean as possible and create space for social distancing between patients in line and at the register, as well as sealing off the pharmacy when possible.

**Toilet Paper for All**
Considering the nationwide toilet paper shortage, Nancy Peterson, RPh, owner of Clearwater Pharmacy in Clearwater, Kansas, had a great idea. “We are asking each homebound delivery whether they need toilet paper. Our local grocery store donated 12 packs. Our mayor offered to help deliver if needed. Our police officers offered to deliver, as have several patients. I just love my little town!” she shared.

**Keeping It Clean**
Lisa Hess and Doug Hess, RPh, own Doug’s Family Pharmacy in Elverson, Pennsylvania. Lisa said, “It is amazing the response we have received. People have been so appreciative of our fight to help keep them safe. We spray the cash drawer with Clorox spray, wipe down their credit cards with Clorox wipes, and avoid passing anything unnecessary back and forth. We require our deliveries to be pre-paid with a credit card or put on a store charge. Again, we are keeping both parties as safe as possible. All of our employees have made a pact to self-quarantine to keep each other safe. We are surviving both economically and physically, which makes it so important to have each other’s backs. I’m so impressed with the tolerance and patience of our staff and customers during such a drastic change and trying time.”

**Strong Leadership Is Key**
Trisha Winroth, PharmD, pharmacy manager at Walgreens in Lowell, Massachusetts, stressed the importance of leadership: “Managing a team during the COVID-19 pandemic is no different from managing them through any situation. If they trust in your leadership, the rest falls into place. I give them all the information I have, and I am available to hear their concerns and answer questions. Making my team feel well taken care of is my main goal. We’ve had homemade snacks, plenty of vitamin C, lots of coffee, and a ton of laughs! For us, laughter is really the best medicine, and it keeps us all going throughout any stressful situation. I’m wearing a shirt that says, ‘In a world where you can be anything, be kind.’ I chose it because it’s what we all need through this time. If we all take care of each other and our patients, we’ll come out stronger in the end. Stronger team. Stronger patient relationships. Stronger leaders.”

**Going Above and Beyond for Patients**
Loretta Boesing, a patient advocate, describes ways she has seen pharmacists go above and beyond during the pandemic. “Pharmacy staff are risking their lives to protect their patients. More pharmacists who were silent about the mistreatment of workers and unsafe conditions are breaking their silence about the prioritization of profits before patient safety.” She commended pharmacists who have found creative ways to take care of patients through telemedicine consultations, setting up curbside pickup, demanding proper personal protective equipment, and making hand sanitizer. “Pharmacists and pharmacy staff are there for their communities during this challenging time, checking in on others because they care,” Boesing said.
Communicating With Patients in the Time of COVID-19

By Jenni Zilka, Senior Vice President, Good Neighbor Pharmacy Field Programs & Services, AmerisourceBergen

The coronavirus disease 2019 (COVID-19) outbreak has affected every part of our health care system. Pharmacies, just as expected, have demonstrated meaningful ways to support their communities. We are seeing independent community pharmacies compound hand sanitizer and donate the product to medical facilities, local emergency medical services, and fire and police departments. Many pharmacies are operating closed-door stores and delivering prescriptions right to their patients’ homes. Some are making care packages and donating them to elderly and immunocompromised patients. We are so thankful for all the pharmacists out there who are working on the front lines right now.

Although the effects of COVID-19 are evolving daily, pharmacists, particularly independent pharmacy owners, can do several things to continue supporting patients and providing valuable, fact-based resources about the virus to the community. One way is through simple and effective communication.

Business owners should let patients know of any changes to business hours, expanded delivery services, and whether they have a 24-hour emergency hotline. Posting this information to the pharmacy website, social channels, mobile app, e-newsletters, and voicemail greetings is essential. With social distancing requirements in effect across the country, pharmacists should share information on the different ways in which patients can pick up prescriptions, such as via the drive-thru, curbside pickup, or mail services. If owners are allowing patients into their store, pharmacy staff should proactively share the precautions they are taking to keep patients safe, such as cleaning more frequently and sanitizing high-traffic areas.

For the safety of the community and staff, many independent community pharmacies are operating as closed-door stores. At the same time, many people still have a need for basic household supplies and OTC products, such as vitamins, personal care items, and first aid supplies. If they have ample stock, pharmacies should advertise which OTC products they have available and let customers know that they can be delivered to patients’ homes or are available for curbside pickup. If pharmacies can make their own hand sanitizer, this is a huge resource to the community, and they should advertise its availability as well.

Leveraging patient engagement tools in the pharmacy can help streamline many of these communications. At any time, social media is an essential tool for supporting communications with patients. In today’s environment, social media can connect pharmacies with a large portion of the community without requiring them to come into the pharmacy. In fact, internet activity was up 18% from January to March in the United States, according to Vox.1

Having “office hours” through Facebook Live and taking questions through Instagram are great ways to support the community. Pharmacists are looked to as a source of reputable information. Therefore, owners should refer to verified sources such as the CDC, the World Health Organization, Health & Human Services, and similar organizations on social media.

Pharmacists continue to be named among the nation’s most trusted professions, according to Gallup.2 Although many people are working from home these days, pharmacies continue to operate as essential businesses to ensure patients can get the medications they need. Pharmacists are in a unique position to assist their communities during this COVID-19 epidemic, and they are also able to support the health care community at large.

Important pharmacy services should be authorized and expanded to help deal with the COVID-19 outbreak, which would help increase provider capacity as health care resources are further stressed. This includes granting pharmacists provider status and giving them the ability to test and treat. In this unprecedented era, it’s time to allow pharmacists to practice at the top of their license.3

For references, visit drugtopics.com
A Conversation About Cancer Care During COVID-19

In an interview with Drug Topics®, Robert Brunault, PharmD, a clinical pharmacy specialist in hematology and oncology at Rhode Island Hospital and the Lifespan Cancer Institute, discussed how pharmacies are protecting patients with cancer during the novel coronavirus disease 2019 (COVID-19) pandemic.

DRUG TOPICS®: We’ve heard a lot about flattening the curve and protecting those who are at heightened risk for becoming ill with COVID-19. Is there an elevated risk of contracting the disease for patients with cancer, and does the risk differ depending on the type of cancer?

BRUNAULT: There’s definitely a lot consideration for a patient with cancer, specifically the type of cancer, their place in therapy, the necessity of treatment, and any of the treatment options that they need. I have a couple of examples, one being a patient who needs endocrine therapy for breast cancer versus someone with a newly diagnosed acute leukemia. Both are [patients with cancer], but both, in my opinion, have different factors that would put them at higher or lower risk during these times [when] the virus is circulating. For example, that [patient with breast cancer], their treatment doesn’t require a lot of follow-up, so they’re actually able to have less frequent visits to our infusion center, [which] promotes the social distancing that we’ve all heard about. And the treatment itself that they would be on actually doesn’t compromise their immune system.

On the other hand, if you have [a patient with acute leukemia], their underlying disease state is compromising their immune function. Their treatment, we know, is likely to impact their immune function, as well, and just by the nature of their disease they’re going to need a lot of frequent follow-up here, so they’ll have more contact with people and the health care facility. So I think it’s kind of a loaded question, there [are] a lot of things to consider. I would say yes, it definitely depends on the type of cancer and...where people are in their treatment and what kind of treatment they’re going to be receiving.

DRUG TOPICS®: Can you give us an example of what happens to a patient with cancer, maybe a particular kind of cancer, if they are infected with COVID-19? How does the body respond and how is that different from a person who is not immunocompromised?

BRUNAULT: Sure. I think it goes back to our first 2 examples; for example, the [patient with breast cancer], we know their treatment is not compromising their immune function; their disease state really isn’t compromising it [either], so they’re likely to respond to the virus in a very similar way [as]...the general population....And then if we...go to the opposite end of the spectrum and think of the [patient with leukemia] who doesn’t have an existing immune system, they’re probably likely to have more of a severe course, just because at baseline they don’t have an ability to fight off the infection.

DRUG TOPICS®: And how should pharmacists counsel patients with cancer to avoid contracting COVID-19?
**DRUG TOPICS®**: What do you think are the biggest concerns right now regarding health-system pharmacists and COVID-19?

**BRUNAULT**: I would say probably the biggest concern for everyone within the health care system is just the lack of or difficulty acquiring personal protective equipment. So I think especially in these times, we need to be prepared—as hospitals and as a country and the health system as a whole—ensuring that all our hospitals can get the necessary personal protective equipment. So I think that’s probably a concern that’s at the forefront of most people’s minds, but again I think our hospital and a lot of hospitals that I’ve heard about are taking necessary precautions and really trying to promote social distancing, telemedicine, and things like that.

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**DRUG TOPICS®**: What are you hearing from the front lines in terms of how this pandemic has affected workflow with health care systems? For example, are pharmacists being asked to do more hours or stockpiling medications, or are there other changes that you have heard about or experienced yourself?

**BRUNAULT**: There have been a lot of changes that have happened. I would say as far as pharmacy operations, and specifically within our infusion center, we’re really trying to promote telemedicine where possible...trying to avoid having patients unnecessarily coming into a health care facility, where all these people that are infected are coming in as well. As far as stockpiling medications, typically we recommend not doing that, because you may be taking it from someone else’s supply, so we haven’t really implemented any stockpiling. There are plenty of conversations every day regarding an emergency response and refining our approach and algorithms as to what to do if we contacted patients who may be infected with the virus.

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**DRUG TOPICS®**: Given that there have already been shortages of some injectables, what problems are you foreseeing moving forward into this pandemic in terms of drug production?

**BRUNAULT**: Fortunately our hospital hasn’t had too much difficulty with procurement, but I’ve definitely heard of shortages regarding intravenous opioids, of certain drugs that have been thought to help with some of the symptoms associated with more severe cases of the virus that have ongoing shortages as well. I think right now it’s such a moving target as to which treatments are providing the most benefit, and I think that’s good in a way, because everyone’s trying something a bit different, and that might be a better way of finding something that can be beneficial.
Hydroxychloroquine at the Center of COVID-19 Discussions

Until the outbreak of the novel coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), 2 of the most well-known drug names in the United States were oxycodeone (OxyContin) and sildenafil (Viagra). Everyone has heard of OxyContin thanks to almost 10 years of being linked to the opioid epidemic, and Viagra has become a household name since its release in 1998. There is now a third drug that everyone is becoming familiar with: hydroxychloroquine (Plaquenil). This drug has been discussed by every news media outlet and even endorsed by the president.

Hydroxychloroquine has been available since 1955 as an antimalarial drug. I have at least 6 patients at the pharmacy who have used hydroxychloroquine to manage their rheumatoid arthritis, lupus, and Crohn disease. If you were sitting in my pharmacology class, I’d tell you that it is an antimalarial used as a disease-modifying antirheumatic drug (DMARD). I would tell you it is a cheap drug with good efficacy for some and also that it is 1 of 2 DMARDs that are safe to use in patients with liver failure. You would also learn that it may cause deposition of the drug in the melanin layer of the cones in the retina, underscoring the need for annual eye exams. A cumulative dose of hydroxychloroquine 800 g and being older than 70 years increase that risk. To reach the 800-g level you would have to take 200 mg daily for 11 years, or 400 mg daily for 5.5 years. I would inform you that one of my patients started taking this drug at the end of her pregnancy to prevent a flare-up of her Crohn disease once she delivered, and that neither she nor the baby experienced any adverse effects. If this drug therapy is successful in the treatment of COVID-19, I might have to update my lecture notes.

I have also heard the arguments that this drug is unproven, which for coronavirus treatment is true. COVID-19 has been part of the landscape of our planet for less than 6 months, but what other treatments do we have available? Many of us want placebo trials, but if I am lying in a hospital bed with COVID-19, I do not want a placebo. Remember, we don’t placebo-test parachutes!

Many people feel we shouldn’t be using an approved drug for an unapproved use. I have one thing to say to them—gabapentin. Gabapentin (Neurontin) was introduced in the United States in 1993; it is currently approved for treatment of postherpetic neuralgia in adults and as adjunctive therapy in the treatment of partial onset seizures in adults and pediatric patients 3 years and older. That’s it, only those 2 indications. I would venture to say that I have less than a handful of patients for whom this drug is prescribed for these approved conditions. We buy our gabapentin in bottles of 500 mg for all strengths, dispensing it for back pain, restless legs syndrome, hot flashes, diabetic peripheral neuropathy, treatment of alcoholic withdrawal, migraines, and mood stabilization. None of these indications are listed on gabapentin’s package insert.

I have to admit that in all 39 years of my career as a community pharmacist, I have never seen a drug that was the center of such intense political discussion. I say, let’s pull all the data from the Centers for Medicare & Medicaid Services on the thousands of patients on Medicare, and examine whether hydroxychloroquine is protective for COVID-19. We should accumulate the data from the rheumatologists who have used this drug on countless patients and the incidence of COVID-19 cases. Then let’s allow the health care professionals to settle the question of the efficacy of a drug that has been around for more than half a century.

“Hydroxychloroquine has been available since 1955 as an antimalarial drug.”

By Peter A. Kreckel, RPh

In My View / Dispensed as Written

Peter A. Kreckel, RPh, practices community pharmacy in Altoona, Pennsylvania.
Fam-trastuzumab Deruxtecan-nxki for HER2-Positive Unresectable or Metastatic Breast Cancer

By Jennifer Akosa, PharmD/MBA Candidate 2020, and Lisa M. Holle, PharmD, BCOP, FHOPA, FISOPP

On December 20, 2019, the FDA granted accelerated approval to fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo).1 The agent is now indicated for treating adults with unresectable or metastatic HER2-positive breast cancer who have received 2 or more prior anti-HER2–based regimens in the setting of metastasis.2 Fam-trastuzumab deruxtecan-nxki is a humanized immunoglobulin G1 HER2-directed antibody and topoisomerase inhibitor conjugate attached to a cleavable linker.1 These mechanisms of action enable the drug to target HER2 changes that promote cancer proliferation as well as link to a topoisomerase inhibitor, a chemical compound toxic to cancer cells.

Efficacy

The approval of fam-trastuzumab deruxtecan-nxki stemmed from results of the phase 2 DESTINY-Breast01 trial (NCT03248492) of fam-trastuzumab deruxtecan-nxki monotherapy in patients with HER2-positive metastatic breast cancer.3 The trial enrolled 184 women with HER2-positive, unresectable and/or metastatic breast cancer who had received 2 or more prior anti-HER2 therapies in the metastatic setting (median, 6 therapies; range, 2–27). Patients received fam-trastuzumab deruxtecan-nxki every 3 weeks. The primary end point of overall response rate (complete and partial responses), verified by independent central review, included 60.9% (95% CI, 53.4–68.0) of patients, with a median duration of response of 14.8 months (95% CI, 13.8–16.9). Within this population, there was a 6% complete response rate (n = 8) and a 54.9% partial response rate (n = 103).

Safety

Fam-trastuzumab deruxtecan-nxki has a black box warning for interstitial lung disease (ILD) and pneumonitis, including reports of fatal cases. Monitor for and promptly investigate signs and symptoms including cough, dyspnea, fever, and other new or worsening respiratory symptoms. The drug should be permanently discontinued in patients with grade 2 or higher ILD/pneumonitis. An additional black box warning concerns embryo-fetal toxicity. Advise female patients of reproductive potential to avoid breastfeeding and to use effective contraception during treatment and for at least 7 months following the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for at least 4 months after the last dose.3 Fam-trastuzumab deruxtecan-nxki is not interchangeable with the following HER2 products: ado-trastuzumab emtansine, conventional trastuzumab, and trastuzumab/hyaluronidase. Dosing and treatment schedules vary in nature. In certain patients, hypersensitivity reactions (typically delayed) have been reported following exposure to products containing polysorbate 80.1

The most common adverse reactions (≥20%) are nausea, fatigue, vomiting, alopecia, constipation, decreased appetite, anemia, neutropenia, diarrhea, leukopenia, cough, and thrombocytopenia. There are no clinically meaningful drug interactions to report at this time.2 Fam-trastuzumab deruxtecan-nxki may increase patient risk of developing left ventricular dysfunction as decreased left ventricular ejection fraction has been observed with anti-HER2 treatments.1

Dosage and Cost

Dosage is 5.4-mg/kg intravenous infusion once every 3 weeks (21-day cycle) until there is disease progression or unacceptable toxicity.2 For delayed or missed doses, administer as soon as possible (do not wait for the next planned cycle). Adjust the administration schedule to maintain an interval of 3 weeks between doses. No dose adjustments are recommended for mild to moderate renal or hepatic impairment. No data are available in severe renal or hepatic impairment. The cost per 100-mg single-use vial is $2755.1

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www.RxBrokerage.com

Tony Hayslip, ABR/AREP
713-829-7570
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Ernie Zost, RPH
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