2020 Opportunities
and Headwinds in Pharmacy

TECHNOLOGY
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VACCINES
A Conversation With NVAC Chair Robert H. Hopkins Jr, MD

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Optimizing Pill Disposal Programs

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Nutrition Counseling Tips

2020 YEAR IN REVIEW

PLUS

ADDRESSING DRUG DIVERSION

TOP DRUG APPROVALS, PRODUCTS OF 2020

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As coronavirus disease 2019 (COVID-19) cases skyrocket across the United States and reach record numbers, health care professionals are braced for a potentially tough winter season ahead. Although many of us are relieved for 2020 to come to a close, COVID-19 isn’t going anywhere for the sake of the new year.

However, over the last month, both Pfizer and Moderna reported promising early efficacy results for their respective COVID-19 vaccine candidates. The announcements expelled a beacon of hope for an approved vaccine in the near future, but there is still much work to be done. Drug Topics® will continue to monitor as these developments unfold, so keep an eye out for more coverage on the progress of COVID vaccines and how pharmacies can prepare. For now, you can find our interview with Dr. Robert H. Hopkins Jr, MD, chair of the National Vaccine Advisory Committee, about an impending COVID-19 vaccine on page 14.

This issue brings together a comprehensive look at key trends and highlights from the year. For starters, read our Annual Pharmacy Salary Survey results on page 8. From compensation to stress levels to overall job satisfaction, Drug Topics® surveys pharmacists each year to check the pulse of the industry regarding important workplace issues. To no one’s surprise, pharmacists are facing higher stress levels than ever before, as workloads increase and job satisfaction dips. The results certainly reflect the whirlwind year that 2020 proved to be.

And for more highlights, on page 20 you can find our article on the 2020 drug approvals and product launches that pharmacists are most excited about.

As we near the year’s end, Drug Topics® would like to thank you for engaging with our digital and print content throughout the year. As the most accessible health care team members with an expanding list of responsibilities, pharmacists have certainly faced a unique set of challenges this year. We hope to continue to support you by providing meaningful content aimed at helping you navigate the ever-changing landscape of the profession. Look for us online at drugtopics.com and in print.

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Both Pfizer and Moderna recently reported promising phase 3 study results evaluating their respective messenger RNA vaccines for coronavirus disease 2019 (COVID-19).

Pfizer and BioNTech’s vaccine, BNT162b2, met all of the study’s primary efficacy end points, with the analysis of the data indicating a vaccine efficacy rate of 95%, according to final results. Additionally, the vaccine showed an observed efficacy over 94% in adults older than 65 years of age.

Moderna reported results from an interim analysis of its phase 3 study for mRNA-1273. At press time, results showed that the vaccine demonstrated a 94.5% efficacy rate. Additionally, no significant safety concerns were reported. The interim analysis incorporated observation of 95 cases: 90 cases of COVID-19 in the placebo group and 5 cases in the mRNA-1273 group.

FDA Fast Tracks Novavax’s COVID-19 Vaccine Candidate

The FDA has granted fast track designation for Novavax’s vaccine candidate for coronavirus disease 2019 (COVID-19).

The designation for NVX-CoV2373 was based on preclinical and clinical trial data; the former showed induction of the antibodies that block binding of spike protein to receptors targeted by the virus and the latter phase 1 portion demonstrated that the vaccine candidate was well-tolerated and produced antibody responses more robust than results from convalescent sera, according to the Novavax news release.

The company is also evaluating NVX-CoV2373 in a phase 3 trial in the United Kingdom, as well as 2 ongoing phase 2 studies, a phase 2b trial in South Africa, and a phase 1/2 continuation in the United States and Australia.

ThoughtSpot 2020 Series
Supporting Marginalized Communities During Natural Disasters

For our first episode in the ThoughtSpot 2020 series, experts from AmerisourceBergen and Healthcare Ready discuss how to support marginalized communities amid pandemics and natural disasters.

As part of our partnership with Good Neighbor Pharmacy (GNP) and AmerisourceBergen, we welcomed guest host Susan Lorenz-Fisher, vice president of Corporate Citizenship at AmerisourceBergen, who interviewed Gina Clark, president of the AmerisourceBergen Foundation, and Nicolette Louissaint, executive director and president of Healthcare Ready, on the topic of supporting marginalized communities amid the coronavirus disease 2019 pandemic and natural disasters.

“When we think about the range of things that pharmacists are trained to do, and the fact that 93% of Americans are within 5 miles of a pharmacy, they’re the closest type of health care in the United States to most people, especially those who are in rural or traditionally underserved communities,” Louissaint said.

“For us, they’re a critical part of all disaster responses. And as such, we have to make sure that first and foremost, they have the resources that they need to be able to continue to operate.”

To listen to this podcast and others, visit www.drugtopics.com/podcasts.
Officials with Operation Warp Speed recently announced that they expect 40 million doses of an anticipated coronavirus disease 2019 (COVID-19) vaccine to be available by the new year.

The distribution is enough to vaccinate about 20 million Americans at high risk for COVID-19, Department of Health and Human Services (HHS) Secretary Alex Azar, MD, said in a news briefing.

The CDC has moved to facilitate rapid distribution of vaccine to each state, Gen. Gustave Perna, OWS chief operating officer, said in the briefing. Perna mentioned McKesson, in addition to Pfizer and Moderna, as partners in distributing the vaccine.

“We will begin distribution of the vaccine within 24 hours after emergency use authorization is approved,” Perna said. The government is planning to deliver COVID-19 vaccine weekly to each state.

Once investigators and the FDA determine the safety and efficacy of the vaccine, “every jurisdiction will have access immediately,” Perna added.

“There is light at the end of the tunnel,” Azar said. “But we need people to get there.” Azar said continuing to practice good individual behaviors—washing hands, social distancing, wearing masks, and avoiding crowded spaces—remain critical in protecting against COVID-19.”

AstraZeneca’s COVID-19 Vaccine Meets Primary End Point

By Gabrielle Ientile

Results of an interim analysis for AstraZeneca’s coronavirus disease 2019 (COVID-19) vaccine, AZD1222, demonstrated that the vaccine candidate met the primary efficacy end point in preventing COVID-19 infection.

The United Kingdom-based study evaluated 2 dosing regimens. The first, in which the vaccine is administered as a half dose followed by a full dose at least 1 month later, showed 90% efficacy.

The other regimen, which included 2 full doses at least 1 month apart, demonstrated 62% efficacy, according to the analysis. Overall, investigators reported an average vaccine efficacy of 70%, with all results deemed statistically significant.

The analysis, which included data from the COV002 phase 2/3 trial in the UK, as well as the COV003 phase 3 trial in Brazil, also reported no hospitalizations or severe cases of COVID-19.

More than 23,000 participants are being assessed in the 2 clinical trials, with the studies also taking place in the US, Japan, Russia, South Africa, Kenya, and Latin America. Investigators expect to enroll up to 60,000 participants worldwide.

AZD1222 was co-created by the University of Oxford and Vaccitech through the use of a replication-deficient chimpanzee viral vector based on a weakened version of adenovirus, a common cold virus that contains the specific gene material of the severe acute respiratory syndrome coronavirus 2 virus spike protein.

As a result of the findings, AstraZeneca intends to submit AZD1222 to receive emergency use listing status from the World Health Organization, which would facilitate the vaccine’s availability and uptake in low-income countries.

US Expects 40 Million Doses of COVID-19 Vaccine by End of Year

By Gabrielle Ientile

Officials with Operation Warp Speed recently announced that they expect 40 million doses of an anticipated coronavirus disease 2019 (COVID-19) vaccine to be available by the new year.

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2020 BASE SALARY

Q: WHAT IS YOUR CURRENT HOURLY WAGE?

SATISFACTION WITH CURRENT POSITION

17% Extremely dissatisfied
27% Somewhat dissatisfied
26% Satisfied
15% Very satisfied
16% Extremely satisfied
By Jennifer Barrett

Each year, Drug Topics® surveys pharmacists on important workplace issues—from compensation encompassing salary, wages, and raises to stress levels and overall job satisfaction.

For our 2020 survey, we received 1037 responses from pharmacists. This year undoubtedly posed new challenges for pharmacy amid the coronavirus disease 2019 (COVID-19) pandemic, and our findings underscore the effects.

Compensation

As far as compensation goes, pharmacists are still largely making close to what they made in previous years.

Salary versus hourly pay was nearly evenly split between respondents, with 50.4% of pharmacists reporting an annual salary and 49.57% receiving compensation on an hourly basis.

In 2020, the majority of pharmacists who responded to the survey reported earning a salary of more than $120,000 or an hourly wage more than $61. The number of pharmacists with salaries in the $100,000 to $130,000 range in 2020 seems to be closely aligned with that from 2019: 38% reported making that amount in 2020, compared with 40% in 2019. A total of 39% of pharmacists in 2020 reported earning more than $130,000 per year, compared with 50% in 2019.

Further, 41% said they received additional income in 2020. The highest earners reported an extra $15,000 or more on average, but most respondents reported between $1001 to $5000 in extra income.

In terms of raises, 35% of pharmacists received a raise in 2020; of those individuals, the majority received raises between 1% and 3%.

Are pharmacists happy with what they make? That depends. Twenty percent listed income as one of their reasons for considering a job change. The following results on stress and job satisfaction levels hint that even these salary ranges may not be enough to offset increasing workloads and frustrations with current workplace challenges.

DrugTopics.com
Stress and Workload

Management pressure, high work volume, endless amounts of paperwork—all of these are part of a pharmacist’s job, which unfortunately often leads to job-related stress. Compounded with the ongoing pandemic and high patient demand, it is no surprise that pharmacists are generally feeling more overwhelmed this year.

Our survey results showed that pharmacists reported higher stress levels and increased workloads in 2020 compared with previous years.

Seventy-three percent indicated increased stress levels in 2020 compared with 61% in 2019. Pharmacists cited higher work volume (79%), COVID-19 (67%), and more pressure from management (65%) as the highest stressors. Another 73% said their workload has increased, up slightly from 70% in 2019, and just 20% reported that their workload has remained the same.

Although COVID-19 has likely exacerbated this trend, high stress and heavier workloads have been steadily affecting the profession for years. Pharmacists are increasingly taking on larger roles in the care of their patients, while also facing additional pressures such as direct and indirect remuneration (DIR) fees and low reimbursements.

When asked why their stress levels have increased at work, many pharmacists submitted responses ranging from insufficient staffing support, issues with pharmacy benefit managers (PBMs), and lack of training to the explosive growth of vaccinations.

Job Satisfaction

Although the majority of pharmacists earn at least $120,000 per year, 44% reported being dissatisfied with their current position and 35% are considering a job change as a result.

Overall, 56% selected being either “satisfied,” “very satisfied,” or “extremely satisfied” with their current position. Even though 25.6% reported being “satisfied” with their job, 27% indicated that they were “somewhat dissatisfied.” Moreover, the percentage of pharmacists who said they were “extremely dissatisfied” jumped from 9% in 2019 to 17% in 2020.

Insufficient support, high stress, and the belief that they are not receiving adequate compensation are all factors that roll into low job fulfillment. As anticipated, the added burdens of increased workload volume, inadequate support staff, and frustrations around DIR fees and unfair PBM practices contribute to the likelihood of job dissatisfaction.
Nutrition Counseling Tips for Patients With Autoimmune Conditions

Pharmacists can play an integral role in educating patients about nutrition and lifestyle factors. By Jennifer Gershman, PharmD, CPh

Autoimmune diseases are on the rise globally, and recent studies have revealed that the prevalence of antinuclear antibodies (ANA), common biomarkers of autoimmunity, have significantly increased in the United States. Pharmacists can play an integral role in counseling on nutrition and lifestyle factors associated with autoimmune diseases.

Nutrition Tips
Emerging evidence suggests that vitamin D deficiency may play a role in autoimmune diseases. Pharmacists can advise patients with autoimmune diseases to have their vitamin D levels checked to determine whether supplementation is needed. Vitamin D can be obtained through sunlight, food, and supplements. However, sunlight exposure can increase the risk of skin cancer. Adults under 50 years of age should have 400 to 800 international units (IU) of vitamin D daily, whereas individuals 50 years and older should take 800 to 1000 IU daily. Generally, it is difficult to obtain adequate vitamin D through diet, so supplementation is needed.

Patients with lupus should consume a nutritious, well-balanced diet that includes fresh fruit and vegetables, whole grains, and moderate amounts of meat, poultry, and fish. They should avoid alfalfa sprouts, which contain the amino acid L-canavanine, which can increase inflammation. Remind patients to always consult their pharmacist prior to starting any herbal supplements, as some can exacerbate autoimmune diseases. One example is echinacea, which has been reported to cause flares in patients with lupus and other autoimmune conditions. Pharmacists can educate patients with celiac disease about following a gluten-free diet, as they should consume only foods and beverages with a gluten content less than 20 parts per million. Gluten is a protein found in wheat, barley, and rye that can damage the lining of the small intestine in patients with celiac disease. Naturally gluten-free food groups include fruits, vegetables, meat, poultry, seafood, dairy, beans, legumes, and nuts. Patients with celiac disease often have vitamin deficiencies, so taking a multivitamin, along with calcium and vitamin D supplementation, is important.

Limited evidence suggests that the autoimmune protocol (AIP) diet can improve symptoms of certain autoimmune diseases, such as Hashimoto thyroiditis and inflammatory bowel disease. The AIP is an elimination diet that focuses on avoiding foods with added sugar or other additives that can cause inflammation. Food groups are gradually reintroduced back into the diet to determine if any reactions occur. Elimination foods generally include grains, legumes, nightshades (e.g., tomatoes, potatoes, peppers, eggplant), dairy, eggs, coffee, alcohol, nuts, seeds, refined or processed sugars, and oils, as well as food additives. More research is needed because eliminating certain food groups can lead to nutrient deficiencies.

For references, visit drugtopics.com.
The best practices for pill disposal are always being updated and policies vary from state to state. Opioids, in particular, are a concern and pharmacists are being called upon to educate their patients on optimal disposal practices.

Community pharmacist Elizabeth Skoy, PharmD, an associate professor at North Dakota State University School of Pharmacy in Fargo, said consumers can look for medication take-back events or drop off unused or expired medications at their local law enforcement office. Some pharmacies provide products that patients can mix with medications before disposing of them, or envelopes they can use to mail a medication to a facility for incineration. “There often is a cost to the patient for these options. There are also states that allow consumers to bring unused or expired medication to kiosks located near their local pharmacy. North Dakota allows for kiosks at the pharmacy, and tons of medication have already been collected and disposed of within the state,” Skoy told Drug Topics®.

This issue is now at the forefront because it is estimated that more than half of individuals using prescription pain relievers for nonmedical purposes obtain the medications from a friend or relative.1 Skoy said children or pets can access medications left in medicine cabinets or trash cans, which can cause unwanted, even life-threatening adverse effects. She noted that individuals looking to obtain medication for nonmedical purposes often check these areas, making proper disposal paramount.

What About Opioids?

Policies for opioid disposal vary by state. Community pharmacists should contact their state board of pharmacy to identify disposal options and what may be available for their particular pharmacy location. The FDA has a flush list, which includes opioids and other medications that the agency has identified as being suitable to flush as a method of disposal.2 According to the FDA, the known risks from accidental exposure to these medications far outweigh any potential risk to humans or the environment that may arise by flushing them. “If someone is unable to properly dispose of unwanted medications through any of the above disposal options, and the medication is not on the FDA flush list, the last [option] is to dispose of [it] at home. To do this, you can mix the medication with cat litter, coffee grounds, or dirt and then place the mixture in a sealed plastic bag before discarding in the trash can,” said Skoy.

Lisa Schwartz, PharmD, who is the senior director of professional affairs at the National Community Pharmacists Association (NCPA) in Alexandria, Virginia, advises pharmacists to counsel each patient to do what works best for them to keep their

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**Optimizing Pill Disposal Programs**

Counsel patients on best practices for disposal of unused or expired pain medications. John Schieszer
“The National Association of Boards of Pharmacy has an online search tool where consumers can search for a drop box near them.”

“By disposing of medications in a secure drop-off bin, usually at a pharmacy or law enforcement agency, or using a prepaid medication disposal mailer, you also help protect the environment, especially the lakes and rivers,” Schwartz said.

Amy Tiemeier, an associate professor of pharmacy practice at St Louis College of Pharmacy at University of Health Sciences and Pharmacy in St Louis, Missouri, said the best way for a consumer to get rid of unused or expired medications would be to dispose of them in a medication drop box or at a take-back event that destroys medications in an EPA-certified incinerator. “Drop boxes can be found throughout the country and long-term care facilities didn’t go into effect until October 2013. “It was at least 6 months after that before any large chains started putting drop boxes in some of their locations, and some states had laws that still didn’t permit it. With the addition of more medication drop boxes that were more widely available to the general public, the recommendation changed to using that method first if available instead of flushing,” she explained.

For references, visit drugtopics.com.

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As 2020 draws to a close, several coronavirus disease 2019 (COVID-19) vaccine candidates are making their way through the pipeline, raising several questions about administration and distribution once a vaccine reaches approval. Drug Topics® interviewed Robert H. Hopkins Jr, MD, chair of the National Vaccine Advisory Committee, about COVID-19 vaccines.

Drug Topics®: Where are we at in the stages of the development of a COVID-19 vaccine?

Hopkins: Well, I think we’re making a great deal of progress. We currently have 5 vaccines that are in the phase 3 trial process or getting ready to start in the phase 3 process. And those are not typical phase 3 vaccine trials. These are phase 3 vaccine trials with 30,000 or more participants. We’re going to have a lot of data on these vaccines.

I am hopeful that we’ll have at least the first 1 or 2 of those submitted to the FDA for evaluation, either under a biologic license agreement or biological license assessment process, or through the emergency use authorization process that FDA has laid out specifically related to COVID-19 vaccines.

And I think, based on some of the preliminary reports, we’re likely to have at least 1 or 2 of those vaccines submitted to FDA for evaluation before the end of the year. I don’t think we’ll reach 300 million doses available for injection by the end of the year, which was one of the targets, but I think that we will have made tremendous progress toward that by the end of this calendar year.

Drug Topics®: What is the current thinking in terms of how these vaccines will be rolled out?

Hopkins: Well, the CDC and state health departments and other public health agencies around the country are communicating, I’m sure on an… if not weekly…almost daily basis, on developing their plans for distribution.

I’ve looked at our state plan for Arkansas. We are looking at widespread collaborations between the health department and those of us at academic medical centers and other places, talking about how we’re going to get a vaccine out and disseminated.

One of those challenges is going to be what degree of cold chain we need to maintain, how cool we need to keep that vaccine. I think there are going to be a limited number of facilities that will be able to stock hundreds or thousands of doses of vaccine that [have] to be kept at –25 or –70 degrees °C. And I think that’s going to drive a lot of the dissemination processes.

Our institution, and I’m sure many others around the country, are having discussions around detailed
plans on how we’re going to start vaccinating those tier 1A workers. Are you going to start with folks in the ICU, the ER, the nurses, the doctors, the respiratory therapists? I think all of those decisions are going to have to be made locally.

But we’ve all got to be open minded. We’ve all got to be collaborating. And we’ve all got to be continuing to learn what we know about the current vaccines so that we’re best prepared to implement [goals] once we get vaccines.

Drug Topics®: Regarding that collaboration in health care, what do you see as the pharmacist’s role in facilitating COVID-19 vaccinations once they are available?

Hopkins: I see a number of critical roles. Number 1, if we think about vaccine storage and being able to get it from...a health department to an institution, you’ve got to have appropriate storage. Our pharmacists are often going to be on the front line of making sure we’ve got the right refrigeration and freezing processes to maintain that cold chain.

Our pharmacists and our clinicians, physicians, and nurses will need to collaborate very closely on making sure that we track giving the appropriate [COVID-19] vaccine, particularly if you have a 2-dose series,...to each individual that gets the first dose of a vaccine, [ensuring] that they get the second dose of the correct vaccine.

We all have to be talking about the particular characteristics of a particular vaccine when it’s available. I see the pharmacist’s role [as being] as integral as our nurses’ and physicians’...if we’re going to be successful in this campaign.

Drug Topics®: How can pharmacists address patient questions about the safety and efficacy of vaccines?

Hopkins: I think we need to focus on 3 factors. [Importantly], the vaccine development process for these COVID vaccines requires all of the same steps that we normally require to approve any vaccine in this country. You have to go through preclinical studies, you have to go through phase 1, phase 2, phase 3 studies. And equally importantly, after the vaccine is approved under emergency use or a license application, there’s the phase 4, which is [the] ongoing evaluation of safety in that vaccine once it gets into the community. Those process steps remain.

What we’ve done with [OWS] is instead of having those being in a series, in a line along a graph, many of those steps are now being done in parallel. By doing it in parallel, we don’t skip a step; we maintain all of those same steps, but we do them at the same time. That increases cost, because not only are we doing those evaluation steps, but we also [have] factories being geared up to produce these vaccines. If a vaccine turns out not to be effective, or unsafe, that’s lost. We’re not going to use an unsafe product or a product that doesn’t work.

We’re investing a lot of money to make these processes happen in parallel, but we’re not skipping steps. We’re going to evaluate the safety of these vaccines very carefully through the federal process as well as [through] experts from outside of the federal government....I think we need to reinforce those messages, that while we’re going to start with vaccines [that are] not available for everybody that wants [them], we will start with a tiered set of recommendations. We will move from highest priority, meaning highest risk first, to wider use as soon as we have vaccines available. And we all need to work together to make that happen and protect as many people as possible as quickly as possible.

Editor’s note: This interview transcription has been edited for style and clarity.

Visit drugtopics.com to watch the full video interview.
Telepharmacy began as a pilot project to bring pharmacy services to rural North Dakota communities too small to support a full-time pharmacist. Two decades later, telepharmacy is an everyday reality across the country. The concept remains the same: a pharmacist in one location provides services electronically to patients in another location. But pharmacists, providers, patients, prescribers, payers, and regulators are all recognizing the benefits that virtual services can bring to pharmacy.

There is a wide spectrum of needs that telepharmacy can meet, according to Adam Chesler, PharmD, MBA, the director of regulatory and legislative affairs for Cardinal Health and former vice president of operations at TelePharm, an early telepharmacy technology provider. Cardinal acquired TelePharm in 2016 and is now among the largest telepharmacy technology providers in the United States.

Do you have a deaf patient who needs an American Sign Language consultation? How about freeing up pharmacists for clinical activities or to spend more time on immunizations? Telepharmacy does all that and more, and can be further used to:

- Balance work load across multiple pharmacy locations
- Open an urban location that seems unlikely to support a pharmacist
- Take over an independent pharmacy whose owner is ready to retire
- Provide pharmacy services inside a physician practice or clinic
- Consult with patients who can’t leave home
- Bring pharmacy services to disaster relief and homeless shelters

“We have seen a surge in remote consultation, especially during COVID-19 [coronavirus disease 2019],” Chesler said. “Patients needed telepharmacy more than ever when physician offices were closed and pharmacy was the only place to get any kind of access to care. The reality is that we can have a pharmacist just about anywhere to get questions answered on prescription or OTC medications, get an interactions check, adjust therapies for patients, [or] verify a product before dispensing. Telepharmacy puts pharmacists in the cloud. That means they can be anywhere that you ever wanted a pharmacist to be.”

**Balance the Load**

Devin Trone, PharmD, took a familiar route into telepharmacy. He used telepharmacy out of one of his Medicap Pharmacies in Meridian, Idaho, to provide remote services for a new store in Garden Valley, a rural mountain town about 50 miles away. Pharmacy technicians in the new store took care of customers, while a touchscreen video link brought in a pharmacist as needed to check prescriptions before dispensing, provide consults, and answer patient questions.

“It didn’t take us long to realize we could use the same telepharmacy system as part of our quality control workflow for all our prescriptions,” Trone said. “We have 4 locations, so you know that some aren’t as busy as the others. Instead of having scripts back up on the busier location, why not use telepharmacy to distribute the workflow? Putting all of our pharmacists in the cloud helps keep any one pharmacist from getting

Continued on Page 19 >
PUTTING PHARMACISTS IN THE CLOUD / TECHNOLOGY

< CONTINUED FROM PAGE 16

overloaded. Telepharmacy gives pharmacists more time with patients and cuts wait times at all of our locations.”

With 4 stores, Trone has at least 3 pharmacists in the cloud during all open hours. But even the smallest location doesn’t depend entirely on telepharmacy. All 4 locations have a pharmacist physically on site at scheduled times. It helps remind patients that there really is a pharmacist available, he explained. And there are some services, such as immunizations, that can only be provided in person.

What can be done virtually and what must be done in person depends on the state, Trone said. In Idaho, technicians who have completed a certification program may provide immunizations under the supervision of a pharmacist, which can be done virtually. But in Oregon, for example, where Trone also has a pharmacy, immunizations can only be administered by pharmacists.

Telepharmacy is also an easy route to growth. Taking the pharmacists out of the local workflow and putting them in the cloud removed them from the physical dispensing flow. What no one had recognized is that they had been doing part of the technicians’ jobs as well as their own.

“When we put our pharmacists in the cloud, we discovered that 40% to 50% of their time had been spent on mundane things like stuffing bags, stickering, applying labels,” Trone said. “Working in the cloud helps them focus on pharmacist-only activities. We could easily add another 500 prescriptions a day without making our pharmacists work harder. We will be able to continue growth without over taxing or adding pharmacist labor.”

**Expand Hybrid Pharmacy Services**

NuCara focuses on rural, small-town health care with pharmacies in Illinois, Iowa, Minnesota, North Dakota, and Texas. The company looks at telepharmacy as a tool to improve patient care and extend the reach of pharmacists. But instead of relying entirely on virtual services, NuCara is developing a hybrid model that combines telepharmacy with in-person pharmacist services to provide the best of both.

“We had the second pilot telepharmacy in Iowa, a little town called Zearing, population 500,” said Brett Barker, PharmD, vice president of pharmacy at NuCara Management Group. “When we got into telepharmacy, we were looking at the majority of rural independent pharmacies in the Midwest being owned by pharmacists in the later stages of their career. They wanted an exit strategy, but they didn’t want to abandon their communities. Telepharmacy can meet both those goals.”

The obvious approach is to take over an existing pharmacy from the retiring owner and convert directly to telepharmacy operations, Barker continued. But telepharmacy also offers more options and more flexibility. Some rural pharmacists had cut their operations to half-days, whereas others split their time between retail operations and the local hospital.

A town of 500 may not be able to support a full-time pharmacist, Barker said, but there is no lack of demand for pharmacy services. A small medical clinic in Zearing had a call list of 3 dozen pharmacies that patients used that were within a 60-minute driving radius.

Few patients were using any one pharmacy consistently, Barker said. Which pharmacy they used for which prescription depended on where they had to go that day or week. And if they didn’t have to go to a larger town, they may not have filled a prescription at all.

“What we were seeing was patients using a combination of mail order, whatever happened to be in prescribers’ sample closets, multiple pharmacies, and maybe not getting to a pharmacy at all,” he explained. “And that’s definitely not better. Telepharmacy can bring all those prescriptions to 1 place, with 1 pharmacist or 1 group of pharmacists looking at them all. And even if you don’t have a pharmacist in town every day, you have technicians who know the patients who can oftentimes identify problems they can refer to the pharmacist.”

However, the flexibility that telepharmacy can provide is not a panacea, he continued. A live pharmacist in the pharmacy is still the gold standard for pharmacy practice, but that isn’t always economically viable. Telepharmacy gives patients and providers options they might not have had before.

“Obviously, there’s a learning curve for patients and prescribers,” Barker said. “But people grasp the concept immediately especially with the broad push for telehealth services during COVID-19. We also train our technicians to walk patients through the process because there are people out there who have never used a touchscreen device before. Patients get so used to remote counseling that they walk right up to the station expecting to use it. It’s a surprise on days when we have a pharmacist on site and they can talk to the pharmacist in person.”

“The hybrid telepharmacy model maintains a pharmacist in those locations at least part of the time and pharmacy services all the time,” he continued. “Too many people think ‘all or nothing’ when it comes to telepharmacy. Just like there’s a spectrum of pharmacy services, there’s an unfulfilled need for pharmacy services, there’s a good chance telepharmacy can help fill that gap.”

For references, visit drugtopics.com.
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Top Drug Approvals and Product Launches of 2020

A look back at the most impressive drug approvals and product launches of the year.  

**By Keith Loria**

Coronavirus disease 2019 (COVID-19) news may have dominated headlines for most of the year, but there were plenty of other noteworthy drug and product launches in 2020 that pharmacists were excited about.

**New Drugs**

As of late October 2020, First Databank (FDB) has added 75 new drug applications (NDAs), 223 abbreviated new drug applications (ANDAs), and 27 biologics license application (BLA) approval numbers to its MedKnowledge drug database. At press time, the FDA has approved 42 novel drugs, 62 first-time generics, and 45 medical devices in 2020.

Hussam Hamoush, PharmD, pharmacy manager and owner of Stonelbriar Pharmacy in Frisco, Texas, called clascoterone (Winlevi; Cassiopea) cream 1% a huge breakthrough in acne treatment because it is the first medicine offering a nonantibiotic approach. The FDA approved clascoterone on August 27 and Cassiopea expects the drug to launch in early 2021.

“[The] fewer antibiotics that we use, the less chances there are of more drug-resistant bacteria,” Hamoush said. “This is a whole new approach in treating acne using a different mechanism of action. This will be huge for people that have had a lot of trouble with acne in the past.”

He also noted that rimegepant (Nurtec ODT; Biohaven Pharmaceuticals), which was approved on February 27, is a great drug for patients with migraine, as it only needs to be taken once to resolve migraine attacks in less than 1 hour. “It’s a quick-dissolve tablet and with just 1 dose, it can prevent migraines for up to 48 hours,” Hamoush said.

In addition to rimegepant, lasmiditan (Reyvow; Eli Lilly and Company) and ubrogepant (Ubrovy; Allergan USA) have also been impactful for migraines this past year, as there have been no therapies with a novel mechanism of action for acute migraine treatment since triptans were first approved over 20 years ago.

Julie Suko, PharmD, vice president of editorial content at FDB, noted that one of the most effective drugs in 2020 was naloxone, which, if administered quickly, can reverse opioid overdose effects within minutes. “It’s available in several dose forms, but as a nasal spray can be used by untrained persons in case of accidental ingestion of opioids or suspected overdose,” she said. “While it’s not a new drug approval in 2020, the FDA announced new requirements in July to increase naloxone accessibility as an in-home antidote to tackle the opioid crisis head-on. Although different states have varying regulations, most allow naloxone to be furnished directly by the pharmacist, meaning that more patients can gain access to this important and potentially life-saving treatment at the pharmacy counter when they are prescribed opioids.”

Another important new drug is peanut allergen powder-dnfp (Palforzia; Aimmune Therapeutics), which is used as oral immunotherapy to mitigate reactions, including anaphylaxis, caused by accidental peanut exposure in pediatric patients aged 4 to 17 years with confirmed peanut allergy.

“This peanut allergen powder is the first drug to be approved in the United States for this indication,” Suko said. “Palforzia requires 3 phases of dosing—initial dosing, up-dosing, and maintenance—and therefore requires a commitment to frequent office visits.”

Another new drug is fostemsavir (Rukobia; ViiV Healthcare), an HIV-1 drug approved for use in combination with other antiretrovirals to treat adults with multidrug-resistant HIV-1 infection who are failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

“This oral extended-release tablet requires baseline and ongoing lab monitoring, including ongoing liver function testing,” Suko said. “It cannot be prescribed in patients with hepatitis B or C.”

Jamie Bearse, CEO and president of ZERO – The End of Prostate Cancer, noted that for the many men across the United States facing advanced prostate cancer, the approvals of olaparib (Lynparza; AstraZeneca Pharmaceuticals) and rucaparib (Rubraca; Clovis Oncology) signify resounding hope and new tools to help them fight for their lives.

“These drugs are the first [poly
According to Ryan Schmidt, PharmD, the associate director of formulary services at Navitus Health Solutions, in 2020 there was a trend of approvals primarily in the specialty space. Most of these products, particularly in the oncology segment, end up being clinically meaningful for the populations they target, but those are often quite small.

However, the approval of elexacaftor/tezacaftor and ivacaftor (Trikafta; Vertex Pharmaceuticals Incorporated) for cystic fibrosis (CF), albeit at the end of 2019, has had a major impact in 2020 for most patients with CF.

“In trials, it showed not only an improvement over existing treatment options, but also efficacy in patient populations for whom treatments had not been available,” Schmidt said. “This has led to a major shift in utilization. Approximately two-thirds of our patients using CFTR-modulating treatments have already switched to Trikafta.”

Another medication that aroused interest upon approval was bempedoic acid (Nexletol; Esperion Therapeutics), designed to lower low-density lipoprotein (LDL) cholesterol.

“As guidelines continue to push for lower goal levels of LDL to help prevent atherosclerotic cardiovascular disease, this potentially adds another option for treatment,” Schmidt said. “However, unlike products such as statins or PCSK-9 inhibitors, trial data regarding the impact of Nexletol on cardiovascular morbidity and mortality are not yet available. When [they are] available, we can expect a higher uptake in the use of this agent.”

### Notable Product Launches

One of the areas that generated increased interest among health care providers in 2020 was digital therapeutics (DTx). “DTx products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease,” Suko said. “DTx products, typically reviewed or cleared by the FDA as software or as a medical device, are an important area to watch. Increasingly, DTx are being prescribed either to augment medication therapy or even as a companion therapy.”

Clinicians use these products in therapeutic areas such as behavioral health, as well as for chronic pain, attention deficit hyperactivity disorder, and heart failure.

DTx are a way to leverage technology to collect active and passive data in between face-to-face appointments. Monitoring takes place via patient-facing apps and sometimes remotely through wearables to evaluate how a patient is doing on a specific medication.

“That feedback can tell a clinician if they need to intervene or change a treatment plan, especially as it relates to changes that may need to be made to a medication or dosage to ensure therapeutically effective therapy,” Suko said. “DTx also can monitor if patients are adhering to their medications, so a clinician can contact the patient if there’s an issue so it can be corrected.”

In the targeted immunomodulatory space, 2 products approved last year—upadacitinib (Rinvoq; AbbVie) and risankizumab-rzaa (Skyrizi; AbbVie)—have had a big push in 2020.

“Although both of these products had not been available, we can expect a higher uptake in the use of this agent.”

### Looking Ahead

As the calendar turns to 2021, pharmacists envision another year full of important drug discoveries and innovative products.

“Fueled by the need for widespread influenza and eventually COVID-19 vaccinations, [there will be] more and more pharmacists administering vaccines, educating people on vaccines and potential [adverse] effects, tracking vaccines via CVX and MVX codes, and much more,” Suko said. “We’ll also be watching for more biosimilar product approvals, which will increase competition and potentially offer cost savings to patients.”

Schmidt indicated that there are other areas on the horizon that should see some additional treatments over the next few years, although the pandemic has definitely created some questions around when approvals may actually happen.

“Although not new medications, ...SGLT2 inhibitors in heart failure could be significant and really expand product use from where it is today,” he said. “Interesting new approaches to HIV also lie ahead, including long-acting preventive medications and new mechanisms of action, which could lead to further advances in this space.”

For references, visit drugtopics.com.
After facing all the headwinds of 2020, pharmacists are gearing up for another year of challenges and change for the profession. But before we jump into 2021, let’s take a look at how they fared over the past year.

Drug Topics® partnered with the Health Care business of LexisNexis Risk Solutions to check the pulse of the pharmacy world and identify key trends from 2020. How has the coronavirus disease 2019 (COVID-19) pandemic affected business operations? As roles shift and responsibility increases, what barriers are pharmacists experiencing and what tools are they using to adapt?

We received 237 responses from pharmacists across all levels and practice settings, who answered questions on issues such as business profitability, immunization, technology, and the effects of COVID-19. The largest proportion of respondents comprised pharmacists at retail chain pharmacies (42%), independent or community pharmacies (29.5%), and health systems (24.5%) (Figure 1).

**Profit Margins Continue to Take a Hit**
Survey respondents were largely concerned about their pharmacy’s profit margins: 72.55% experienced shrinking margins in 2020, with high numbers of respondents pointing to third-party takebacks (recoupment; 62.8%). Concerns also included direct and indirect remuneration fees (58.9%), and pharmacy benefit manager relations or closed networks (55.3%).

**Immunization Demand Brings Challenges**
Pharmacists are finding themselves at the center of an explosive growth in vaccination needs, especially with an anticipated COVID-19 vaccine on the horizon. However, many pharmacies are not yet prepared to expand patient outreach.

Even as the declaration under the Public Readiness and Emergency Preparedness Act expanded pharmacists’ ability to vaccinate children aged 3 to 18 years, 63% of pharmacists indicated that the new rule did not change their pharmacy’s strategy for outreach. Moreover, although 61% of pharmacies plan to administer COVID-19 vaccines once available, less than half plan to conduct patient outreach apart from instore signage to promote vaccinations.

Most pharmacists perceive several challenges associated with offering COVID-19 vaccines (Figure 2).

**FIGURE 2. Challenges With COVID-19 Vaccines**

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product availability</td>
<td>82.4%</td>
</tr>
<tr>
<td>Customer demand</td>
<td>59.3%</td>
</tr>
<tr>
<td>Tracking of dosing regimens administered per patient for vaccines requiring initial dose</td>
<td>56.4%</td>
</tr>
<tr>
<td>Reimbursement by third-party payers</td>
<td>52%</td>
</tr>
<tr>
<td>Storage of product</td>
<td>43.1%</td>
</tr>
<tr>
<td>Not offering COVID-19 immunizations</td>
<td>7.4%</td>
</tr>
</tbody>
</table>

Despite more than half of pharmacists identifying dose tracking as a significant barrier, 88.7% of respondents said they do not currently employ an outside vendor to assist with patient immunization tracking and/or outreach.

**Opportunities Arise for Data, Technology**
A greater focus on patient data analytics may lead to a much more comprehensive approach to treating patients in the pharmacy and ultimately drive improved outcomes.

The COVID-19 pandemic has placed an even greater urgency on pharmacists to adopt models of Social Determinants of Health (SDOH). SDOH, per the CDC, are data values that summarize where a person lives, learns, works, and plays. To accelerate patient engagement efforts, pharmacies can integrate SDOH analytics to gain a better view of the whole patient.

Fourteen percent of pharmacists who responded to the survey reported using SDOH as a competitive differentiator to improve patient care. The most commonly available SDOH reported in patient records were housing type, household demographics, and area crime index, as well as education level, area of study, and professional licenses, according to the survey.

Furthermore, the pandemic has underscored the importance of technology to enhance patient care, as many pharmacies have pivoted to a virtual means of communication. According to the survey, 43% of pharmacists said their pharmacy currently offers telepharmacy services. These services range from remote order entry or verification (22%) to remote patient counseling (20.5%) and Medication Therapy Management services (36%).

**Patient Mobility Adds Burden to Health Record Management**
Almost one-third (30%) of respondents noticed an increase in patient mobility in 2020, defined by a change of address and contact information, which 84% believed was influenced by COVID-19. However, as patients became more mobile, this placed an added burden on pharmacies’ ability to efficiently manage patient
health records. More than half of respondents reported a noticeable trend to this effect, and indicated that this increased mobility made it more difficult to maintain accurate health records.

**Mail-Order Pharmacy Expected to Increase**
Although most pharmacies (60%) offering mail-order prescriptions did not observe an uptick in that area of their business in 2020, more than 70% expect additional growth in the coming year.

However, more than 85% of pharmacies foresee a greater risk of fraud around mail-order prescriptions, mostly associated with patient addresses for prescription delivery (35%). Other concerns for potential fraud center around prescriptions from unauthorized providers and patient identity fraud (Figure 3).

**COVID-19 Pharmacy Regulations Invoke Change, Uncertainty**
Approximately half of pharmacists believe that the COVID-19–related regulations put into effect for pharmacies are likely here to stay, at least until spring 2021, according to survey responses. Such rules enacted under the emergency declaration address certain prescribing and dispensing requirements, point-of-care testing, and vaccine administration.

Pharmacists largely did not experience any compliance-related issues (66%) with such regulations; however, the majority (78%) of those who did reported confusion regarding prescribing activities that are permitted during the emergency declaration. This was followed by almost 40% of pharmacists who cited an increase in inappropriate payer rejections (Figure 4).

Despite **56.4%** of pharmacists identifying dose tracking as a significant barrier, **88.7%** of respondents said they do not use an outside vendor to assist with patient immunization tracking and/or outreach.

**What’s Next?**
Overall, 2020 ushered in changes in pharmacy business models brought on by the pandemic. COVID-19 has certainly accelerated the transformation of pharmacy, as pharmacists adjust to disruptions in health care delivery, but the road ahead remains filled with barriers.

On the regulatory side, clarifications are needed to solidify pharmacists’ role as care providers in the community and ensure the viability of their businesses. To keep up with the ever-changing health care landscape, pharmacists will need to tap into technology now more than ever to optimize their care delivery and improve efficiencies as their responsibilities grow.

*This survey was brought to you by Drug Topics® and sponsored by the Health Care business of LexisNexis Risk Solutions.*
In the US, health care leaders are so overwhelmed by the clinical, operational, and financial aspects of managing coronavirus disease 2019 (COVID-19) that they may be less focused on stopping drug diversion. But it is still happening. In many parts of the country, opioid-related overdoses are rising while health care workers on the front lines are reporting higher levels of mental health issues. Meanwhile, the supply of coronavirus treatments, within a strained economy, could increase their black market value.¹,² Yet the biggest signs of the potential for drug diversion to skyrocket in health care environments may be within the hospitals themselves, which have been forced to quickly adapt to the COVID-19 era.

Since March, the spread of COVID-19 has fueled a higher sense of urgency in health care centers, from the movement of nurses from one hotspot area to the next to related increases in patients with high-acuity needs. This has led to the implementation of new rules, workflows, and guidelines, to ensure that contact with high-risk individuals is minimized, personal protective equipment is appropriately rationed, and frontline workers receive the support they need.

Although these operational shifts were necessary, they have exposed new vulnerabilities in care settings.

Here are 5 tactics health care leaders can employ to improve their efforts in stopping drug diversion:

1. **Broaden awareness.** Clinical leaders are already having conversations about drug diversion, but it is important to keep the issue top of mind among clinicians. Sharing news of recent incidents highlights not only the theft of COVID-19–associated supplies, but also the criminal consequences.

2. **Retrain as needed.** If the physical layout of a health facility was modified in response to COVID-19, clinicians may need to be retrained on adapting medication management practices to a new environment. For example, Drug Enforcement Agency guidelines require that unused controlled substances must be destroyed following strict rules, so clinical supervisors may need to take extra steps to ensure compliance.³

3. **Focus on data.** Discrepancies in data, such as patient pain scores, may indicate the need for a diversion investigation. Case in point: In May, an Iowa nurse anesthesiologist was sentenced to 34 months in prison for tampering with vials of fentanyl in a hospital’s surgery and birthing center. But the nurse’s drug problem was only discovered by accident when a hospital visitor caught him sleeping. Only when authorities reviewed his obstetrics patients did they learn that 1 in 4 of the nurse’s spinal anesthesia patients had received narcotics that were insufficient to reduce labor pain. Had a red flag been raised sooner, the perpetrator would have potentially been investigated more quickly.⁴

4. **Consult an expert.** A dedicated drug diversion professional, used on a part-time or full-time basis, can assess a health care facility’s current approach and solutions to mitigating drug diversion and identify gaps. Yet according to a 2020 study conducted by Porter Research and Invistics, just 41% of health care organizations have at least 1 dedicated diversion professional on site.⁵ Considering that only 36% of workers surveyed said they are confident in their organization’s drug diversion program, having an expert available to support efforts to improve drug diversion could be a game changer.

5. **Broaden visibility** In addition to having visibility into the supply chain, it is important to have visibility into other areas, including health care workers’ experience and background, adjustments in the workflow, and so on. A health care organization may want to consider using technology (eg, track and trace software) or increasing the number of audits it performs on a regular basis.⁶

For references, visit drugtopics.com.

**Tom Knight, MBA, MS** is the CEO and founder of Invistics, a provider of inventory visibility and analytics software solutions.
Advocating for Independent Community Pharmacies on Federal and State Levels

To keep their pharmacies viable during this time, pharmacists can continue to advocate on both federal and state levels to address specific issues that would affect them and their patients. By Jennifer Barrett

Many of the challenges that independent pharmacies have faced for years have become even more apparent during the coronavirus disease 2019 (COVID-19) pandemic, highlighting the need for action in several legislative areas.

During ThoughtSpot 2020, Good Neighbor Pharmacy’s annual independent community pharmacy conference and trade show which is being held virtually this year, Bob Mauch, PharmD, RPh, Executive Vice President and Group President of AmerisourceBergen, and Beth Mitchell, Senior Director of Government Affairs for AmerisourceBergen, talked with Drug Topics® about the importance of advocacy during this time and the legislative priorities that independent pharmacists should keep an eye on for the future.

The COVID-19 pandemic has highlighted areas of needed legislation that can benefit pharmacists, their businesses, and their patients. To keep their pharmacies viable during this time, pharmacists can continue to advocate on both federal and state levels to address specific issues that would affect them and their patients. Since March, AmerisourceBergen and Good Neighbor Pharmacy (GNP) have met with more than 300 federal and state legislators and staff through video and phone calls, continuing to make an impact on pharmacy policy priorities amid COVID-19.

Expanded Immunization Authority

The Department of Health and Human Services’ (HHS) just authorized pharmacists to order/administer COVID-19 vaccinations (once available) to persons age 3 and older. In August, HHS also authorized state-licensed pharmacists to order/administer all CDC recommended and FDA approved vaccines for children ages 3-18, aiming to ensure stronger vaccine access for children during the pandemic. HHS was able to authorize this under the Public Readiness and Emergency Preparedness Act and both measures ensure stronger vaccine access for individuals in the US. The authorizations also aim to preempt state and local laws that prohibit or effectively prohibits those who satisfy requirements from ordering or administering vaccines.

“This news is a huge win, but we’re still pushing for more,” Mauch told Drug Topics®. “These actions are certainly good steps in the right direction and they show that the government is thinking about the important role that pharmacists and community pharmacy can play in the immunization process, but it should be much more broad, frankly to include empowering and reimbursing pharmacists for providing immunizations and other services to patients during and beyond COVID-19.”

In addition, several questions remain about how pharmacists will be reimbursed by payers for this service. Mauch noted that GNP and AmerisourceBergen will continue to work with manufacturers and pharmacy partners in several pharmacy trade associations and the American Disease Prevention Coalition to monitor these concerns.

Mitchell noted that the HHS announcements are positive developments for both patients and pharmacists, but improvements are still needed. “We’ve got to do more,” she said. “We have to think about how we need as many access points for all vaccinations as possible. Pharmacists are so well positioned to do this.”
Keeping Up With Continuing Education Is a Must

Pharmacists must recognize the importance of continued learning in the profession.

I've been writing for Drug Topics® for over 6 years now, but May 2014 wasn’t the first time my work was published. Back in 1982, I engaged with the then president of Rite Aid in a debate about the need for continuing education (CE) in pharmacy. He argued that he didn’t see the difference between pharmacists in states that required CE versus those in states that did not. After my first year of practice, I began to realize that keeping up with the latest clinical information wasn’t optional, but mandatory.

I recall reading that a pharmacy school dean once told the students that 50% of what they learned would be obsolete in 5 years. I share that statistic with my physician assistant students at the end of the year and they cringe. When I show my 6th year student pharmacists around the pharmacy and point out which drugs I learned about in school, they are amazed that accounts for only about 10% of what is on the shelf. One of my students asked, “So what did they teach you in pharmacy school?” I retorted, “They taught us how to learn!”

When I graduated in 1981 there were no angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). Now I give pharmacy students a “laundry list” of drugs that are on our “fast mover” shelves, such as atenolol, metformin, duloxetine, fluoxetine, alendronate, atorvastatin, and simvastatin.

My son-in-law Mark lives on a mountain top in West Virginia, where cutting grass with a push mower is nearly impossible. Mark hired a landscaper named Jerry to take over grass-cutting duties. Jerry’s Facebook page has beautiful pictures of his handiwork, but what is most impressive is how Jerry posts pictures of himself sharpening his blades and maintaining his equipment. When Jerry isn’t planting, seeding, cutting grass, or mulching, he spends a lot of time making himself better at his noble profession. Jerry isn’t mandated to sharpen his blades every day, but his desire to do a great job helps retain his customers. Similarly, keeping up with CE allows pharmacists to sharpen their own tools.

Mandatory CE is part of everyone’s licensing requirements; however, I do believe that in some circumstances, certain CE disciplines may not be necessary depending on one’s practice. Boards of pharmacy mandate certain CE disciplines such as opioids and HIV. In Pennsylvania, all health care professionals (and even funeral directors) are required to complete 2 hours of mandatory child abuse reporting. Some states require suicide recognition and human trafficking courses to renew licensure. Not that I don’t see a purpose in such courses, but they certainly should not be mandated for all subspecialties of this profession. I have a mandatory 2-credit requirement for immunization because I’m an immunizing pharmacist. That makes sense.

One of my many frustrations with most free CE venues is that they seem to be drug company sponsored. You can find free programs if you want to focus on glucagon-like peptide-1 agonists, proprotein convertase subtilisin/kexin type 9 inhibitors, the newest insulins, or monoclonal antibodies. Trying to find a CE program featuring ACE inhibitors, ARBs, beta blockers, or OTC therapies at no cost is virtually impossible.

At age 62, I’m a lifelong learner. I feel no different than I did as a 23-year-old who debated in Drug Topics® with the president of Rite Aid. I have a lot less years of practice ahead of me than I did then. However, I feel more passionately than ever about the unmet educational needs of us community pharmacists.

We need to learn a lesson from Jerry the landscaper; we need to sharpen our tools every single day.

Peter A. Kreckel, RPh, practices community pharmacy in Altoona, Pennsylvania.

“I feel more passionately than ever about the unmet educational needs of us community pharmacists.”
The most common adverse reactions (≥ 10%) were nausea, vomiting, diarrhea, fatigue/asthenia, constipation, pneumonia, abdominal pain, arthralgia, decreased appetite, febrile neutropenia, dizziness, and pain in extremities. Because of the potential for myelosuppression, monitor complete blood counts (CBCs) every other week for the first 2 cycles and prior to starting each cycle thereafter. Azacitidine may cause fetal harm. Women are advised not to breastfeed during treatment with azacitidine and for 1 week after the last dose. Pregnancy testing is recommended for women of reproductive potential before starting azacitidine, and they should use effective contraception during azacitidine treatment and for 6 months after the last dose. Men should use effective contraception during treatment with azacitidine and for 3 months after the last dose. Azacitidine is associated with an increase in early mortality in patients with myelodysplastic syndromes. Treatment of these patients with azacitidine is not recommended. Do not substitute azacitidine for intravenous or subcutaneous azacitidine (due to substantial differences in pharmacokinetic parameters and indications). No reported drug interactions exist at this time.

Both 200 mg and 300 mg tablets are available. The recommended dose is 300 mg orally once daily with or without food on days 1 through 14 of each 28-day cycle. A dose reduction to 200 mg orally once daily is recommended for severe myelosuppression, or grade 3 or 4 nausea, vomiting, diarrhea, or other toxicity. Continue azacitidine until disease progression or unacceptable toxicity. Administer an antiemetic 30 minutes prior to each dose of azacitidine for the first 2 cycles. Antiemetic prophylaxis may be omitted after 2 cycles if there has been no nausea and vomiting. The cost per 200-mg and 300-mg tablet is $1813.55. The cost for one 28-day cycle of azacitidine therapy is $25,389.70.
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The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older.

Limitations of Use:

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINdications

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates the reactions will occur in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (24.9%) subjects were aged 50 to 59 years, 4,486 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were white (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), swelling (25.3%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%), respectively.

The reported frequencies of specific solicited local adverse reactions and general adverse events (overall per subject), by age group, from the 2 studies are presented in Table 1:

<table>
<thead>
<tr>
<th>Group</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHINGRIX %</td>
<td>Placebo %</td>
<td>SHINGRIX %</td>
</tr>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
<td>82.8</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10.3</td>
<td>0.5</td>
<td>6.9</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
<td>38.4</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
<td>26.5</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

a 7 days included day of vaccination and the subsequent 6 days.

b Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

c Placebo was a saline solution.

d Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

e Grade 3 myalgia, fatigue, headache, shivering, GI: Defined as preventing normal activity.

f Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as ≥39.0°C/102.2°F.

g GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

(continued on next page)
The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The majority of solicited local adverse reactions and general adverse events seen with SHINGRIX had a median duration of 2 to 3 days.

There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 13.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 50.5% and 32.0% of subjects who received SHINGRIX (n = 14,645) and placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (3.5% versus 0.2%), injection site pain (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX and placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) and placebo (2.2%) from the first administered dose up to 30 days post last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 38°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

Deaths

From the first administered dose up to 30 days post last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

Potential Immune-Mediated Diseases

In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

Dosing Schedule

In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

General Disorders and Administration Site Conditions

Decreased mobility of the injected arm which may persist for 1 or more weeks.

Immun System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

8.5 Geriatric Use

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse events in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years) [see Adverse Reactions [6.1]].

17 PATIENT COUNSELING INFORMATION

• Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.

• Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.

• Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Storage:

Store vials of Lyophilized gE Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the vials have been frozen.

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October 2019 SHX:4BRS

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SGXJR/NA200009 August 2020

Produced in USA.
SHINGRIX DELIVERED >90% EFFICACY AGAINST SHINGLES REGARDLESS OF AGE IN THOSE 50 YEARS AND OLDER \(^1,\ast\)

### Images do not depict actual patients

*Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials in subjects who received 2 doses of SHINGRIX (N=7344 and 8250, respectively) or placebo (N=7415 and 8346, respectively) and did not develop a confirmed case of herpes zoster within 1 month after the second dose.\(^7\)

### Study 1 Design:
Data from ZOE-50—a placebo-controlled, observer-blind, phase 3 trial conducted in 18 countries in which subjects ≥50 years old were randomized to receive 2 doses (0 and 2 months) of either SHINGRIX (N=7698) or placebo (N=7713). A total of 7344 and 7415 subjects who received SHINGRIX and placebo, respectively, were included in the modified Total Vaccinated Cohort (mTVC) analysis.\(^12\)

### Study 2 Design:
Data from ZOE-70—a placebo-controlled, observer-blind, phase 3 trial conducted in 18 countries in which subjects ≥70 years old were randomized to receive 2 doses (0 and 2 months) of either SHINGRIX (N=6850) or placebo (N=6950). A total of 6541 and 6622 subjects who received SHINGRIX and placebo, respectively, were included in the mTVC analysis.\(^14\)

The primary efficacy analysis (mTVC) in Studies 1 and 2 included all subjects who did not develop a confirmed case of HZ within 1 month after the second dose.\(^1\)

**Pooled Analysis:** Data from ZOE-50 and ZOE-70 were combined in a pre-specified pooled analysis. A total of 8250 and 8346 subjects ≥70 years of age who received SHINGRIX and placebo, respectively, were included.\(^1\)

The studies excluded subjects who were immunocompromised, had a previous history of HZ, were previously vaccinated against varicella or HZ, and patients whose survival was not expected to be at least 4 years, or with conditions that might interfere with study evaluations.\(^1\)

### Important Safety Information (cont’d)

- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%).
- Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%).
- SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion.

---

**Table:**

<table>
<thead>
<tr>
<th>AGE</th>
<th>Efficacy (95% CI)</th>
<th>Shingles cases (n) in SHINGRIX group (N)</th>
<th>Shingles cases (n) in placebo group (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50–59†</td>
<td>96.6% (89.6, 99.3)</td>
<td>3 (3492)</td>
<td>87 (3525)</td>
</tr>
<tr>
<td>60–69†</td>
<td>97.4% (90.1, 99.7)</td>
<td>2 (2141)</td>
<td>75 (2166)</td>
</tr>
<tr>
<td>70–79‡</td>
<td>91.3% (86.0, 94.9)</td>
<td>19 (6468)</td>
<td>216 (6554)</td>
</tr>
<tr>
<td>≥80‡</td>
<td>91.4% (80.2, 96.9)</td>
<td>6 (1782)</td>
<td>68 (1792)</td>
</tr>
</tbody>
</table>

\(^1\) Data from ZOE-50 phase 3 trial.\(^1\)

\(^2\) Pooled data from ZOE-50 and ZOE-70 phase 3 trials.\(^1\)

\(^7\) CI=confidence interval; n=number of subjects having at least 1 confirmed herpes zoster episode; N=number of subjects in each group.

---

**References:**
1. Data on file, GSK.
4. Prescribing Information for SHINGRIX.
SOLICITED ADVERSE REACTIONS\textsuperscript{1,4}

<table>
<thead>
<tr>
<th>LOCAL ADVERSE EVENTS*</th>
<th>SHINGRIX (N=4884)</th>
<th>Placebo (N=4880)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>78.0%</td>
<td>10.9%</td>
<td></td>
</tr>
<tr>
<td>Pain, Grade 3\textsuperscript{1}</td>
<td>6.4%</td>
<td>0.3%</td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td>38.1%</td>
<td>1.3%</td>
<td></td>
</tr>
<tr>
<td>Redness, Grade 3\textsuperscript{1}</td>
<td>2.9%</td>
<td>0%</td>
<td></td>
</tr>
<tr>
<td>Swelling</td>
<td>25.9%</td>
<td>1.0%</td>
<td></td>
</tr>
<tr>
<td>Swelling, Grade 3\textsuperscript{1}</td>
<td>1.0%</td>
<td>0%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GENERAL ADVERSE EVENTS*</th>
<th>SHINGRIX (N=4876)</th>
<th>Placebo (N=4881)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Myalgia</td>
<td>44.7%</td>
<td>11.7%</td>
<td></td>
</tr>
<tr>
<td>Myalgia, Grade 3\textsuperscript{3}</td>
<td>5.1%</td>
<td>0.7%</td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>44.5%</td>
<td>16.5%</td>
<td></td>
</tr>
<tr>
<td>Fatigue, Grade 3\textsuperscript{3}</td>
<td>5.3%</td>
<td>1.0%</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>37.7%</td>
<td>15.5%</td>
<td></td>
</tr>
<tr>
<td>Headache, Grade 3\textsuperscript{3}</td>
<td>3.3%</td>
<td>0.7%</td>
<td></td>
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<tr>
<td>Shivering</td>
<td>26.8%</td>
<td>5.8%</td>
<td></td>
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<tr>
<td>Shivering, Grade 3\textsuperscript{3}</td>
<td>4.1%</td>
<td>0.3%</td>
<td></td>
</tr>
<tr>
<td>Fever\textsuperscript{2}</td>
<td>20.5%</td>
<td>3.0%</td>
<td></td>
</tr>
<tr>
<td>Fever, Grade 3\textsuperscript{3}</td>
<td>0.3%</td>
<td>0.2%</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Symptoms\textsuperscript{2}</td>
<td>17.3%</td>
<td>8.7%</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Symptoms, Grade 3\textsuperscript{3}</td>
<td>1.4%</td>
<td>0.6%</td>
<td></td>
</tr>
</tbody>
</table>

*Main safety pooling analysis. ZOE-50 and ZOE-70 studies. Incidence of solicited general symptoms reported during the 7-day (i.e., day of vaccination and subsequent 6 days) post-vaccination period, overall/subject (Total vaccinated cohort with 7-day diary card; subjects ≥50 YOA).

\textsuperscript{1}Significant pain at rest; prevented normal everyday activities.

\textsuperscript{2}>100 mm.

\textsuperscript{3}Prevented normal everyday activities.

\textsuperscript{4}Temperature ≥95.5°F (≥35.8°C).

\textsuperscript{5}Temperature >102.2°F (>39.0°C).

\textsuperscript{6}Including nausea, vomiting, diarrhea, and/or abdominal pain.

N=number of subjects with at least 1 documented dose; YOA=years of age.

To see the CDC Recommendations about vaccination, visit us at AgingSHINGRIX.com

Important Safety Information (cont’d)

• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see additional Important Safety Information throughout and Brief Summary of Prescribing Information for SHINGRIX on the previous pages.


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RECOMMEND SHINGRIX WITH CONFIDENCE TO PATIENTS ≥50 YEARS OLD

SHINGRIX (ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

In the pivotal clinical trials, the most common solicited adverse reactions observed were pain, redness, and swelling at the injection site, myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.

'\( \text{Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials. See study designs on the next page for more details.}'

Indication
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information
• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX

Please see additional Important Safety Information throughout and Brief Summary of Prescribing Information for SHINGRIX on the previous pages.
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Jeff Sherman, PharmD