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Another Year Gone, Pharmacists Continue to Weather the Pandemic Storm

As the year draws to a close, we at Drug Topics® have turned our gazes back. We’ve weathered another year of the COVID-19 pandemic; seen the approval and distribution of 3 novel COVID-19 vaccines, as well as campaigns for mass vaccination; and witnessed the transformation of the pharmacy profession in ways we’ve never seen before.

This issue features the results of the Drug Topics® Annual Salary Survey: a comprehensive look at pharmacist’s most important workplace issues. In 2020, pharmacists reported record levels of workplace stress, due in part to an increased workload stemming from the COVID-19 pandemic. This year’s survey results suggest much of the same, with 58.5% of respondents indicating an increase in their stress level at work over the course of the last year. But despite this increase in workplace stress, respondents were split nearly 50-50 when asked if they received a raise during 2021—perhaps suggesting that, nearly 2 years into the pandemic, these health care professionals are still not receiving the support they need.

Despite these workplace challenges, the pharmacy profession continues to advance through innovation: In August, the FDA approved the Pfizer-BioNTech COVID-19 mRNA vaccine (Comirnaty), followed by an October emergency use authorization for that same vaccine in children aged 5 to 11 years. Advances have also been made in the biosimilars market, with 2 FDA approvals of interchangeable biosimilar products—insulin glargine-yfgn (Semglee) and adalimumab-adbm (Cyzelto)—expanding affordable treatment offerings to patients across the country.

As in years past, Drug Topics® would like to thank all our readers for being such an integral part of our publication as we strive to keep our audience at the center of everything we do. Pharmacists continue to face new and unique challenges in their practice, and we look forward to supporting you in your practice into 2022 and beyond.

Thank you for reading,

Mike Hennessy Jr
President and CEO
of MJH Life Sciences™

EDITORS’ NOTE: In our November issue of Drug Topics®, we neglected to credit Bled Marchall Tanoe, PharmD, as the creator of the #PizzaIsNotWorking hashtag. We sincerely apologize for this oversight.

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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.
Consequences of Medical Misinformation Loom Large in Health Care

By Lisette Hilton

The World Health Organization and United Nations have characterized the unprecedented spread of news, public health guidance, fact sheets, infographics, research, opinions, rumors, myths, falsehoods, and more during the pandemic as an “infodemic.” This infodemic has set the stage for exposure to not only accurate, helpful health information, but also to health misinformation, which is false, inaccurate, or misleading, based on the best available evidence at the time.

Misinformation has consequences for quality of care and the provider-patient relationship, according to Brian T. Kelly, MD, Midwest Allergy and Asthma Clinic in Omaha, Nebraska. “Misinformation can result in detrimental decisions throughout the field of medicine. Unfortunately, misinformation is readily available and can appear as fact on many different platforms. I suspect that virtually every physician in the US has conversations with patients each day surrounding some form of misinformation a patient has heard,” said Kelly, who moderated the “Combatting Misinformation in Medicine” panel at the American College of Asthma, Allergy & Immunology (ACAAI) 2021 Annual Scientific Meeting, held November 4 through 8 in New Orleans, Louisiana. “Combatting this trend through facts and empathy are extremely important to maintain our patients’, communities’, and global health.”

The rise of misinformation has resulted in many problems, according to Kelly. “The COVID-19 pandemic and social media have resulted in extreme levels of misinformation,” Kelly said. “Two of these issues include reduced levels of care, [such as] patients not getting necessary care or procedures like a skin biopsy for possible skin cancer, and an unfortunate distrust in medical providers. It is imperative for physicians to engage and provide factual and rational rebuttals to misinformation, as doing so will only benefit patients.”

The pandemic has highlighted the pervasive nature of health-related misinformation and how it can negatively impact medical decision-making, according to David Stukus, MD, a pediatric allergist and professor of clinical pediatrics in the division of allergy and immunology at Nationwide Children’s Hospital in Columbus, Ohio, and participant on the medical misinformation panel at ACAAI. “Patients often seek medical information online, and unfortunately, the social media algorithms emphasize emotion-generating headlines, which frequently dilutes out evidence-based facts in favor of inaccurate anecdotes or testimonials,” Stukus said. “All health care professionals need to be aware of the influence misinformation has on their patients. Unfortunately, misinformation was a rampant problem prior to COVID-19 and will persist even after the pandemic is over.”

For references, visit drugtopics.com.
This article originally appeared in our sister publication, *Dermatology Times*.

Every health care professional can take some practical steps to combat misinformation, according to Stukus, which include the following:

1. Use common search engines to learn about the types of sources that appear when common patient questions are searched.

2. Review what evidence-based resources are saying—particularly regarding discrepancies from nonmedical sources.

3. Use every patient encounter as an opportunity to address common sources of misinformation in a nonthreatening manner. Actively listen to what the patient says.

4. Prepare talking points and have resources ready to share with patients. These resources should be concise, clear, and nonjudgmental.

5. Engage on social media to provide evidence-based information and fill the void where expertise is often lost online.
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In 2019, opioid overdoses were responsible for the death of nearly 50,000 Americans, according to the National Institute on Drug Abuse. These opioids—which include prescription pain relievers prescribed after surgical procedures—are part of a “serious national crisis” that has impacted everything from public health to social and economic well-being.

Data show that both opioid-naïve and non–opioid-naïve surgical patients are at high risk for chronic opioid use following surgery, but it can be challenging to minimize these risks while appropriately managing postoperative pain. In fact, according to a recent report presented at the American Society of Anesthesiologists annual meeting, 1 in 5 opioid-naïve patients continue to use opioids 3 months after surgery, a statistic that many pharmacists are trying to change.

Joe Moose, PharmD, co-owner of Moose Pharmacy in Concord, North Carolina, and director of strategy and luminary development for CPESN USA, said that starting a patient on opioids comes with the responsibility of setting realistic expectations on what pain management should be and how it should be controlled.

“A patient should be continuously educated on their pain medicine instructions to ensure that they are only taking (the medication) for the necessary amount of time,” he said. “Education...is rarely provided to patients [in a comprehensive way].”

Another significant problem is the irregular, inconsistent enforcement of prescriber limits. Although policies are in place, for both providers and pharmacies, factors like auto-renewals and too-high-of-volume fills both contribute to prolonged, inappropriate use.

Anna Legreid Dopp, PharmD, senior director of clinical guidelines and quality improvement for the American Society of Health-System Pharmacists (ASHP), said that recognized risk factors for opioid misuse or opioid-use disorder (OUD) include a family or personal history of substance abuse, untreated psychiatric conditions, younger age, and social environments that encourage misuse.

“Thanks to our ability to track trends in opioid-use data, we have learned that early prescribing patterns of opioids, especially for those who are opioid naive, [have] significant influence on the potential for long-term use,” Dopp said. “[The] risk of chronic opioid use...increases with each additional day of medication prescribed—starting with the third day This has led to numerous evidence-based policies that limit opioid prescribing to a certain amount of days, often required by institutional, state, or payer policies.”

According to Jim Lichauer, PharmD, BCPS, FASHP, performance improvement program director of pharmacy for Vizient, Inc, prescribed quantities and refills should be limited to 7 to 15 days, or up to 30 days with no refills. “[CDC data] show that the use of prescription refills after a patient’s initial opioid prescription is associated with an increased incidence of persistent opioid use at 1 year,” he said.

The Pharmacist’s Role
Hospital pharmacists can make a difference by conducting a prescription drug–monitoring program (PDMP) search prior to admission, and retail pharmacists can help by assessing current home supply and understanding patient habits by viewing their history of prescribers and early refills, as well as determining the stability of the current regimen.

“Pharmacists need to start setting short-term and long-term goals for pain management, opioid use, and pain expectation,” Moose said. “It is also important to discuss what signs of addiction might look like. Pharmacists should also stress the importance of not leaving medications around the house." Proper disposal prevents children, pets, and others from getting ahold of these medications.

If a patient is still in pain 5 days after their procedure with their current medication, a deeper dive should be conducted into why this might be,
including the possibility that opioids might not be the best course of action.

Pharmacists should engage with the interprofessional care team across the spectrum of pain management, including when opioids are indicated, in the screening for and prevention of opioid misuse, the management of opioid-exposed patients, and the management of patients with OUD.

Pharmacists can manage this collaboration by screening patients for risk factors, educating patients, monitoring PDMPs, building prescribing alerts into electronic health records, and developing policies and protocols to be on alert for potentially risky opioid-prescribing behaviors.

Counseling Matters

Taylor Fortson, PharmD, of Carolina Pharmacy, a Charlotte, North Carolina–based independent group with locations across the Carolinas, noted that pharmacists should provide both medication reconciliation and counseling to assess patient pain and help develop an action plan with physicians to explain to patients how to control postoperative pain safely and effectively.

“Although medication counseling should always be done upon either discharge from the hospital or after surgery, never assume,” she said. “Ask the patient if they have ever taken opioids and review their goals, [adverse] effects, and how to ensure safe use.”

Explain to the patient prescription opioids help relieve short-term pain, but carry a serious risk of addiction and overdose. Fortson typically recommends to patients that they take opioids only for severe pain and use ibuprofen for less severe pain. Fortson generally counsels patients to switch after a few days to alternating between acetaminophen and ibuprofen every 3 to 4 hours.

At Moose Pharmacy, patients are encouraged to read and sign a policy of procedure, which is a key step in opioid counseling. After going over the document and expectations, if a patient is not comfortable, then pharmacists provide counsel on other options and consider a secondary conversation with the prescriber.

Pain management must also be patient centered, said Dopp.

“Including the patient in determining functional pain management goals, identifying therapy options, and setting realistic expectations for treatment will result in buy-in from the patient and their caregiver,” she said. “Something we have been advocating for is to make pain management plans interoperable and accessible to everyone on the interprofessional care team. Doing so enables adherence to the plan throughout transitions of care from the postoperative setting to the patient’s home.”

Simona Dorf, PharmD, BCMAS, clinical pharmacist and editorial manager at First Databank, Inc, which publishes and maintains drug databases for health care professionals, said that some of the most difficult conversations she has had with patients have been on this topic.

“It was never on the first fill,” she said. “It typically occurred down the line with the third fill or later.” Dorf recalled a conversation she had with a patient taking 2 different opioids from different prescribers: 1 for leg pain and 1 for back pain.

Although the patient was adamant that each opioid worked on only that specific pain area, after counseling the patient, Dorf and the patient agreed to discuss the situation with each physician and let them consolidate the pain management regimen.

Making a Difference

Although a physician has to write the prescription, the pharmacist is the gatekeeper. They see their patients more frequently, which provides more opportunity to reinforce the correct medication habits and identify negative adverse effects.

“Pharmacists overall have a closer and more accessible relationship with their patients and the ability to spend time with them,” Moose said. “They also can look into details like where they last received (or) purchased medications to make an assessment on if it might be an escalating situation.”

Robert Alesiani, PharmD, BCGP, chief pharmacotherapy officer at Tabula Rasa HealthCare, once had a patient who underwent a total hip replacement secondary to osteoarthritis and also experienced chronic, episodic lower back pain. The oxycodone prescribed after surgery also helped manage the patient’s back pain, so he continued using it long after the hip healed.

“While he originally self-medicated to improve his function, over time he found himself overmedicated and less functional,” Alesiani explained. “He always seemed to come in for a new fill a couple days early but not so early that the prescription card didn’t pay.”

When the patient came in for a refill, Alesiani pulled him aside and in a nonconfrontational tone asked, “What are you expecting from these medications, and are they working for you?” The response was tearful and surprising: The patient just wanted to get back to normal—and no, the medications weren’t helping.

“After obtaining permission from the patient, I contacted his primary care physician and together, we came up with a plan that included an orthopedic consult,” followed by steroid injections and physical therapy. “After 6 weeks, the patient was taking much less of the opioid and utilizing a COX-2 [inhibitor]. He was more alert, cheerful, and positive. He was still experiencing some pain, but it was manageable.”

For references, visit drugtopics.com.
As initial doses of COVID-19 vaccines made their way into the arms of millions of Americans, health experts and officials turned their thoughts toward the future—namely, toward COVID-19 booster shots. Across the public sphere has been intense debate about the idea of COVID-19 vaccine boosters. Some studies showed dwindling protection over time; other experts felt that booster shots simply weren’t necessary for those who had received a 2-dose vaccine series. Beyond the practicalities of vaccine efficacy, debates also raged about the ethical implications of providing additional protection to those living in wealthy countries while many in low- and middle-income countries had yet to receive even 1 dose.

Ethical and effectiveness debates aside, the Biden administration announced in August a plan to provide COVID-19 booster shots to all Americans 8 months after their second Pfizer-BioNTech or Moderna dose. One month later, a government advisory panel “overwhelmingly rejected Biden’s plan,” backing boosters only for older or high-risk individuals.

In late October, the FDA took the first steps toward delivering boosters to these eligible populations, amending the earlier emergency use authorizations (EUAs) for all 3 COVID-19 vaccines. The FDA and CDC recommended booster administration as follows:

- **Moderna, Pfizer-BioNTech:** One single booster dose may be administered at least 6 months after completion of the initial series to adults 65 years and older and to adults aged 18 to 64 years who live in long-term care settings, have underlying medication conditions, or live or work in settings with a high risk of exposure to SARS-CoV-2.

- **Janssen (Johnson & Johnson):** One single booster dose may be administered at least 2 months after completion of the initial single-dose regimen to adults 18 years and older.

Both agencies also clarified that the COVID-19 booster vaccines are heterologous, allowing patients to mix-and-match based on preference and access. On November 19, the FDA further amended each manufacturer’s EUA, expanding eligibility to all adults 18 and older who completed an initial vaccine series. Timing remains the same: those who received Moderna or Pfizer-BioNTech may receive a booster at least 6 months after initial vaccination, while those who received the Johnson & Johnson vaccine may receive a booster after 2 months.

### The Pharmacist’s Role

For pharmacists concerned about getting booster shots into the arms of eligible patients, Celia Proctor, PharmD, MBA, assistant director for system formulary management and system integration for the Johns Hopkins Health System in Baltimore, Maryland, had some suggestions.

“One helpful tool...is direct messaging to past patients who were previously vaccinated by the clinic,” Proctor said. “Pharmacists can also provide education to patients who are hesitant or who have questions about the need for a booster dose.”

Patients who are hesitant to mix different brands of vaccine can be reminded that the FDA has authorized any of the COVID-19 vaccines to be used as a booster, regardless of which vaccine was received during the initial series, Proctor noted, adding that “education [can be] provided at the clinics as just in time’ information to any patient who may have questions.”

For references, visit drugtopics.com.

“**The FDA has authorized any of the COVID-19 vaccines to be used as a booster, regardless of which vaccine was received during the initial series.”**

CELIA PROCTOR, PHARMD, MBA, OF JOHNS HOPKINS HEALTH SYSTEM
Update: 2021-2022 Flu Season

Influenza is expected to make a comeback this year, and no one knows how severe it may be. By Karen Berger, PharmD

Thanks to COVID-19 infection-control measures, influenza activity was low last year. However, as restrictions ease and lockdowns end, the flu is poised for a comeback.

To help mitigate a surge in cases, the CDC has issued revised flu guidelines for the 2021-2022 flu season.

Updated Flu Vaccine Composition
Every year, the FDA Vaccines and Related Biological Products Advisory Committee recommends an updated flu vaccine composition for flu vaccines in the United States. This season, all flu vaccines will protect against the 4 viruses expected to be most common. There are 2 updates this season compared with last season for influenza A (H1N1) and influenza A (H3N2) vaccine virus components.

All Flu Vaccines Will Be Quadrivalent
A quadrivalent flu vaccine protects patients against 4 different flu viruses: 2 influenza A and 2 influenza B viruses. In previous years, flu vaccines protected against 2 influenza A and 1 influenza B virus. Adding another protection against influenza B provides broader coverage against flu viruses.

Flucelvax Quadrivalent Now Approved in Individuals 6 Months and Older
Patients aged 6 months to 8 years receive either 1 or 2 doses; for patients who need 2 doses—a decision dependent on vaccination history—doses should be spaced apart by at least 4 weeks. Patients 9 years and older will receive 1 dose.

Flu and COVID-19 Vaccines Can Be Coadministered
Pharmacists can feel comfortable recommending and/or administering the flu vaccine at the same time as the COVID-19 vaccine. According to the CDC, “Experimental evidence and extensive clinical experience provide the scientific basis for administering vaccines simultaneously. Simultaneously administering all vaccines for which a person is eligible at the time of a visit increases the probability that a child, adolescent, or adult will be vaccinated fully by the appropriate age.”

When administering the flu and COVID-19 vaccines together, patients should be injected in separate sites—1 vaccine in each arm. If both vaccines must be given in the same arm, the injection site should be separated by at least 1 inch. Documentation should reflect vaccine injection-site locations in case of any reactions.

More Guidance About Vaccine Timing for Some Groups
By now (December), everyone should, ideally, be vaccinated. The CDC recommends vaccination by the end of October; however, patients who have not been vaccinated by the end of October should still get vaccinated because the flu usually peaks in February and can last until May. The CDC now generally recommends the following:

- Adults should not get vaccinated early (in July or August) because protection decreases over time.
- However, if a patient is unable to return at a later date, early vaccination may be appropriate.
- Children should be vaccinated as soon as the vaccine is available, as early as July or August. This helps space the second dose, if needed, at least 4 weeks after the first dose.
- Women in the third trimester of pregnancy may be appropriate candidates for early vaccination.

Updated Contraindications, Precautions for Flucelvax Quadrivalent and Flublok Quadrivalent
If a patient has a history of severe allergic reaction to any flu vaccine, this is now considered a precaution—not a contraindication—for administering the Flucelvax Quadrivalent or Flublok Quadrivalent vaccine. In these patients, vaccination should take place in a medical setting under the supervision of a health care professional who can manage a severe allergic reaction.

For Flucelvax Quadrivalent, a history of severe allergic reaction to any Flucelvax vaccine is a contraindication to future use of Flucelvax Quadrivalent. For Flublok Quadrivalent, a history of severe allergic reaction to any Flublok vaccine is a contraindication to future use of Flublok Quadrivalent.

The 2021-2022 Flu Season: What to Expect
For more information about the 2021-2022 flu season and flu vaccines, Drug Topics talked with Gregg Sylvester, MD, MPH, chief medical officer of Seqirus.
the company that manufactures Flucelvax Quadrivalent.

Although last year’s flu season was comparatively “light,” Sylvester cautioned that that does not necessarily mean this year will be light too. “Although recent data show that this season is starting low, the flu is coming back,” he said. “We don’t know if it will be mild, moderate, or severe. What we do know is that every year we need to vaccinate everyone who is eligible.”

Sylvester noted that many of the precautionary measures for COVID-19, such as mask wearing, hand washing, quarantining, and social distancing, were originally developed for pandemic flu. These measures are helpful for the flu and COVID-19 because both are respiratory viruses and, therefore, will help lower rates of both. “However,” he added, “when we start to congregate and stop wearing masks, various respiratory viruses will spread again.”

Sylvester also encouraged pharmacists to coadminister flu and COVID-19 vaccines to patients when possible. “As a pediatrician, we say, ‘If someone is in front of you and you don’t vaccinate, you miss an opportunity.’” No matter how well-intentioned the patient is, they may not return to the pharmacy as planned.

“The CDC is very clear that coadministration is safe, and we ought to encourage it,” Sylvester said. “Remind patients that mild reactions, like a sore arm or a low-grade fever, mean that their immune system is doing what it’s supposed to do.”

Whether providing a flu vaccine alone or in conjunction with a COVID-19 vaccine, Sylvester reminded pharmacists to ask patients to remain in the building for 15 minutes in case of a severe reaction.

And what about those patients who are reluctant to receive a flu vaccine—or coadministered flu and COVID-19 vaccines? Health care professionals are guided by science and data, Sylvester said, and although they like to reference facts when talking to patients, it may be better to engage in an emotional, personal conversation.

AVOIDING MIX-UPS BETWEEN THE FLU AND COVID-19 VACCINES

With an increasing number of patients receiving both flu and COVID-19 vaccines, including boosters, at the same time, there have, unfortunately, been errors. The Institute for Safe Medication Practices (ISMP) recommends taking the following measures to help avoid mix-ups between the flu and COVID-19 vaccines:

1. Schedule vaccines during times when there is adequate staffing. The staff member who is vaccinating patients should not dispense prescriptions at the same time.
2. Use a separate area for vaccine administration, away from interruptions and other potential distractions.
3. All syringes should be clearly labeled.
4. Only bring the necessary, labeled syringes into the vaccination area, and only bring in syringes for 1 patient at a time.
5. Confirm the patient and the vaccine. When the patient requests the vaccine(s)—and again just prior to vaccination—ask the patient for their name and date of birth. Confirm with the patient which vaccine(s) they will be receiving.
6. Ask the patient or parent to read the syringe label to confirm the correct vaccine is being administered.
7. Record the lot number and expiration date before administering the vaccine. After giving the vaccine, document vaccine administration.
8. Use barcode scanning during production and verification to confirm that the correct vaccine is being used. If possible, use barcode scanning just before administering the vaccine.
9. Report vaccine errors as per company policy. Also, report errors to the FDA’s Vaccine Adverse Event Reporting System and the ISMP National Vaccine Errors Reporting Program.

“If the patient is a grandparent, the pharmacist may say: ‘Fifteen out of every 100,000 people die of the flu—I don’t want the next one to be you. You don’t want your grandkids not to have a grandparent,’” Sylvester added.

“We know that strong recommendations from a trusted health care professional, like a pharmacist or nurse, increase vaccination rates,” Gregg added.

Sylvester added that he would like pharmacists to remember the following takeaways:

- Everyone 6 months and older should get a flu vaccine, unless there is a contraindication.
- Data support the coadministration of the flu vaccine and the COVID-19 vaccine, so pharmacists can feel comfortable administering them at the same time.
- Because the flu is going to return—and we don’t know how severe it will be, especially with COVID-19—pharmacists should encourage everyone to receive the flu vaccine.

For references, visit drugtopics.com.

Karen Berger, PharmD, is a graduate of the University of Pittsburgh School of Pharmacy. Her experience includes chain and independent pharmacy, as well as medical writing and reviewing.

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The COVID-19 vaccine is generally safe and well tolerated in individuals living with rheumatic and musculoskeletal diseases, according to research results presented at ACR Convergence 2021, the annual meeting of the American College of Rheumatology.1-3 "[C]oncerns prevail about the effectiveness and safety of vaccination against COVID-19, especially with respect to triggering [rheumatic and musculoskeletal disease] flares," wrote authors of one abstract.1 For patients and health care providers, these concerns are validated by the knowledge that clinical trials on the safety and efficacy of these vaccines “did not include patients with autoimmune diseases,” according to another team of researchers.2

In the first of 3 abstracts,1 German researchers reviewed data from the observational, longitudinal German COVID-19 vaccination registry, which launched on February 8, 2021. These registry data were voluntarily entered by patients with rheumatic and musculoskeletal diseases who received at least 1 COVID-19 vaccine before May 29, 2021.

Investigators reviewed data from 866 patients (median age, 54 years; 81% women). Fifty percent of patients had been given diagnoses of rheumatoid arthritis, whereas 31% had spondyloarthritis. The most common treatment at the time of vaccination was conventional synthetic disease-modifying antirheumatic drug therapy (59%), followed by glucocorticoids (33%), tumor necrosis factor inhibitors (23%), Janus kinase inhibitors (9%), and IL-17 inhibitors (5%).

Over the previous 12-month period, 42% of patients reported no disease activity, and comorbidities—most commonly arterial hypertension—were present in 40% of patients. The majority of patients in the registry were vaccinated with the Pfizer-BioNTech vaccine (67%), whereas 28% were vaccinated with the AstraZeneca vaccine—which is not yet approved by the FDA for use in the United States. Following the first vaccine, disease flares were indicated in only 13% of participants; within this group, 6% required a change in immunomodulation treatment.

In 41% of these participants, an increase in glucocorticoid dose was sufficient for patients to cope with the flare. These preliminary results, the researchers concluded, “support the recommendation for COVID-19 vaccination” in patients with rheumatic and musculoskeletal diseases.

In the second abstract,2 researchers sought to compare the frequency and severity of adverse events (AEs) after vaccination between patients with autoimmune diseases and healthy controls. Study data were collected via digital questionnaire to participants enrolled in 2 ongoing prospective cohort studies at the Amsterdam Rheumatology and Immunology Center and Amsterdam UMC.

In total, 501 participants with autoimmune diseases (rheumatic disease, n = 420; multiple sclerosis, n = 81) and 184 healthy controls (mean ages, 63 ± 11 years and 64 ± 11 years, respectively; 66% and 65% women) received a Pfizer-BioNTech or AstraZeneca COVID-19 vaccine. A majority of patients in the control group experienced “at least 1 mild AE” (56%
Study Examines Impact of Medical Cannabis on Pain Intensity, Well-being in Fibromyalgia By Gabrielle Lentile

Patients with fibromyalgia experience a multitude of symptoms that aggravate pain, negatively impact well-being, and are often unresponsive to currently available treatments. As a result, patients are increasingly turning to alternative therapies, including medical cannabis, to treat these symptoms. However, there is insufficient data demonstrating the perceived benefits of medical cannabis for this patient population.

Researchers also have not been able to determine which factors lead to continuation of medical cannabis treatment or, conversely, why patients decide to discontinue treatment with medical cannabis.

In the current study, investigators aimed to examine whether changes in negative affect—such as anxiety and depression—and sleep problems influenced pain intensity and well-being following the onset of a medical cannabis regimen, as well as the factors that influenced patients with fibromyalgia to continue treatment with medical cannabis. The study included 308 patients with fibromyalgia, 87% of whom were women (mean age: 52.3±12.9 years), and 54.3% of whom were using a combination of ∆-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

Investigators reported significant improvements in pain intensity and well-being with the initiation of medical cannabis. Data showed that pain intensity decreased with reductions in negative affect and sleep problems. Improvements in well-being were facilitated by reductions in negative affect and pain intensity, authors wrote.

As for the continuation of medical cannabis treatment, the likelihood of treatment discontinuation was higher among patients with more acute pain and negative affect, “but was unrelated to the degree of improvement in these symptoms over the course of medical cannabis treatment,” the authors wrote. At 3 months, 74% of patients had continued their medical cannabis treatment; however, 58.8%, 39.6%, and 23.1% of patients did the same at 6, 9, and 12 months into their treatment course, respectively.

“Our findings suggest that reductions in negative affect and sleep problems are important contributors to improvements in pain intensity and well-being among patients with fibromyalgia using medical cannabis,” the authors concluded. “Discontinuation of medical cannabis was more common among those with higher levels of pain and negative affect but was not related to symptom improvement.”

Disclosures: Multiple authors report industry relationships. For a complete list of disclosures, see the study abstract.

For references, visit drugtopics.com.
As another year of the COVID-19 pandemic draws to a close, pharmacists have begun looking back on the past 12 months and the ways in which the pandemic has impacted their practices, whether big or small.

For the second year, Drug Topics® partnered with the Health Care business of LexisNexis Risk Solutions to take the pulse of US pharmacists and identify the top trends of 2021. This year, 570 survey respondents across pharmacy segments shared their thoughts on topics like out-of-state prescriber regulations, compliance-related issues, and mail-order pharmacy, among others.

THE IMPACT OF NEW RULES AND REGULATIONS
According to survey results, 46.5% of respondents believe that as the COVID-19 pandemic continues to evolve, current out-of-state prescriber regulations will stay as they are currently, whereas 33.1% of respondents feel these regulations will continue to relax. If regulations continue to change, 37.54% pharmacists expect to see changes within the next 6 months.

Compliance-related issues were also top-of-mind this year. More than half of responding pharmacists (56.1%) experienced an "issue" with the change in prescribing rules under the COVID-19 pandemic declaration; these issues included confusion surrounding permissible prescribing activities (43.9%), inappropriate reimbursement recoupment (39.6%), inappropriate payer rejections (37%), sanctions (27.1%), and fines (13.5%).

COMBATING FRAUD WITH MAIL ORDER ON THE RISE
Mail-order pharmacy business is on the rise, with more than half of respondents reporting an uptick in their mail-order business. Respondents were split, however, on their view of mail order in the future: 31% expect additional growth in mail-order pharmacy in 2022, and 34% expect this business to stay the same.

Although mail-order pharmacy ups the convenience factor for patients, some respondents are concerned about the higher risk of fraud associated with the service, specifically 44.1% are concerned about fraud associated with the patient’s address for prescription delivery, 41.5% are concerned about fraud associated with prescriptions from unauthorized providers, and 39.9% are concerned about patient identity fraud. Pharmacists also identified mail theft, “lost” or “damaged” package claims, and physician shopping (patients searching for a physician willing to prescribe a drug off label) as other important concerns associated with sending prescriptions through the mail. One respondent also highlighted their concern about fraud associated with companies imitating new players in the mail-order prescription space like Amazon Pharmacy, whose PillPack service launched in late 2020.

UNDERSTANDING THE INTRICACIES OF IMMUNIZATIONS
As approvals roll in for COVID-19 vaccine boosters, 78.9% of respondents said they work at companies that have a plan to administer these booster shots. However, administration of these shots isn’t without challenges. More than half of respondents cited concerns about managing patient volume at sites that administer both COVID-19 and influenza vaccines, 50.7% are worried about how to avoid creating long wait times through efficient vaccine administration, and 37.8% are concerned about meeting customer demand for these vaccines. Although 25% of respondents have concerns around documentation of COVID-19 booster shots, only half of respondents (51.9%) work at a company that currently uses an outside vendor to assist with patient immunization tracking.

THE NEED FOR SOCIAL DETERMINANTS OF HEALTH DATA HAS NEVER BEEN MORE IMPORTANT
In 2020, social determinants of health (SDOH) entered the public lexicon as the COVID-19 pandemic laid bare the ways a patient’s socioeconomic status can deeply impact health care outcomes. Last year, 14% of survey respondents reported using SDOH as a competitive differentiator to improve patient care. This year, survey respondents are nearly evenly split: 50% report that their pharmacy does incorporate SDOH data into patient records, and 50% report that their pharmacy does not incorporate SDOH data into patient records, and

FIGURE 1. Do you expect additional growth in your mail-order business next year?
49.9% of respondents’ pharmacies still aren’t keeping track. Although more pharmacies are tracking these data through 2021, many pharmacists report not knowing what types of SDOH attributes are available in their pharmacy management system. For those who do keep track, attributes include patient housing type, household demographics, and area crime index (33.2%); education level, area of study, and professional licenses (28.6%); accidents, crime, and convictions (26%); and patient assets, lien, and bankruptcy information (18.9%).

CLINICAL SERVICE OFFERINGS STAY STAGNANT
A majority of respondents (> 60%) report that this year, their pharmacy delivered “about the same” number of clinical services traditionally delivered in other health care settings as in years past. For the 8.4% of pharmacists practicing in pharmacies that increased their clinical service offerings this year, many new services are centered on immunization and other COVID-19–related services such as testing and vaccination. In the new year, 70.7% of respondents said they expect their pharmacies to maintain the current volume of clinical service offerings for patients.

OPPORTUNITIES AND CHALLENGES FOR ENGAGING PATIENTS
For the public, pharmacists are often seen as the most accessible health care professional. This year, however, multiple barriers prevented pharmacists from enhancing or improving patient engagement and care. The most significant barrier was the increased volume of services being provided. As pharmacists’ scope of practice grew, more services translated to less time engaging with the public. An increase in the volume of prescriptions dispensed—coupled with an increase in the volume of patients—also contributed to this lack of engagement. Keeping up with ongoing changes in regulations, filling gaps in patient-level data left out of technology systems, and being hesitant to interact based on personal safety rounded out the reasons why pharmacists felt more disconnected from patients than in years prior.

So what do pharmacists want? According to 32.9% of respondents, they want easier access to a more complete patient record. Respondents are also seeking more certainty when verifying a patient’s identity, more automation, and richer, more complete data about who comes into the pharmacy.

As we look toward 2022, providing these solutions stands to have a positive impact on pharmacist workflow and to increase patient care, outreach, and interaction for the better.
Increased workload and workplace stress did not necessarily translate to increased compensation.

2021 BASE SALARY

Q: WHAT IS YOUR CURRENT HOURLY WAGE?

- $40 or less: 4%
- $41-$45: 8%
- $46-$50: 12%
- $51-$55: 13%
- $56-$60: 15%
- $61-$70: 20%
- $71 or more: 28%

PLEASE INDICATE YOUR ANNUAL BASE SALARY:

- $70,000 or less: 9%
- $70,001-$80,000: 9%
- $80,001-$90,000: 12%
- $90,001-$100,000: 9%
- $100,001-$110,000: 9%
- $110,001-$120,000: 12%
- $120,001-$130,000: 14%
- $130,001-$140,000: 9%
- $140,001-$150,000: 6%
- More than $150,000: 10%
By Lauren Biscaldi

Each autumn, Drug Topics® surveys its readers from across the country to take the pulse of the pharmacy profession before heading into the new year. This year, 1123 respondents were more eager than perhaps ever before to share their feelings on important workplace issues.

**Salary Survey Results**

**Within the Past Year, Has Your Workload:**
- Increased: 62%
- Remained the same: 23%
- Decreased: 14%
- Not applicable: 1%

**Within the Past Year, Has Your Stress Level at Work:**
- Increased: 59%
- Remained the same: 27%
- Decreased: 13%
- Not applicable: 1%

**Job Satisfaction and Workplace Stress**

As we close out the second year of the COVID-19 pandemic, most survey respondents (67.6%) reported that they are satisfied with their current position, whereas just under one-third of respondents reported dissatisfaction with their jobs. Despite this, 42.4% of respondents still indicated that they’re considering a job change within the next 12 months.

Reasons for this potential job change vary. For 18% of respondents, income was cited as the most important factor; for 12.7%, professional development opportunities are behind the change. Issues such as a lack of support from corporate management, work-life balance, and a dearth of support staff in the face of increased COVID-19-related demands are the reason some pharmacists will be searching for greener pastures come 2022.

Most respondents indicated that their workload has increased during 2021 (61.8%); unsurprisingly, stress levels at work have also increased in tandem (58.7%). Increased work volume and COVID-19 were neck and neck as the key driver behind increased stress, with 52.5% of respondents attributing more stress to increased work volume and 52.4% attributing it to COVID-19. Increased pressure from management, increased paperwork, a negative workplace environment, and lack of training were also cited as drivers of increased stress. Those who indicated “other” as the reason pointed to a lack of pharmacy technicians and other trained staff, unrealistic expectations, and patient hostilities due to wait times and copays as the main drivers of daily stress.

When asked what factors contributed to a decrease in workplace stress this year, 22.9% cited additional technology support, 21.2% cited improved workplace environment, 20.4% cited increased staffing, and 14.9% cited more...
employee-sponsored training. A little more than 30% of respondents, however, opted to share their own response to the question, indicating that over the past 12 months, stress levels have not decreased at all.

**Salary and Compensation**

Most respondents to this year’s survey were industry veterans (32.4%), with 25 or more years on the job. Most respondents were employed as staff pharmacists (32.3%), followed by pharmacy department managers (14.3%), clinical pharmacists (12.1%), and store owners or partners (9.7%).

Respondents were nearly evenly split between receiving an annual salary or hourly wage, with slightly more respondents (51.6%) receiving hourly pay. Current hourly wages for most pharmacists were between $61 and $70 an hour; only 20.1% received $71 an hour or more.

For those respondents receiving an annual salary, most were paid between $110,001 and $120,000 (14.1%) per year, followed closely by $100,001 to $110,000 (12.3%) and $90,001 to $100,000 (11.7%); only 10.3% of respondents reported making more than $150,000 per year. Regardless of how they’re paid, 51.2% of respondents reported not receiving any additional income—in the form of commission, bonuses, or profit sharing—in 2021.

Despite an increase in work volume and subsequent workplace stress, raises were not a certainty—for some. Respondents were split nearly evenly: 50.2% received a raise in 2021 and 49.7% did not; this was an increased from our 2020 survey, when only 35% of pharmacists reported receiving a raise during the worst of the COVID-19 pandemic.

**Demographics and Methodology**

The Drug Topics® annual pharmacy salary survey was available online from October 20 to November 15 and received a total of 1123 responses. A little more than half of the respondents were men (52.1%); 25.5% practice pharmacy in the Southeast United States and 58.7% were employed full time. Most respondents were employed at either chain or independent pharmacies—19.5% and 18.7%, respectively—and 16.2% reported employment in a hospital pharmacy setting.
For years, expanding a pharmacist’s scope of practice has been top of mind for those in the profession. By the time the COVID-19 pandemic hit the United States in early 2020, community pharmacists were ready to mobilize and engage in direct patient care.

“The pandemic required a number of time-sensitive, health-driven initiatives to run nationally, but with a coordinated focus at the local level,” said Paige Clark, RPh, vice president of pharmacy programs and policy at Prescriptive Health in an interview with Drug Topics®. “Luckily, we as community pharmacists are built for such a challenge.”

Direct patient care by community pharmacists is particularly critical during a public health emergency like the COVID-19 pandemic, Clark added. Realizing this, the US government moved quickly to engage these health care providers to provide COVID-19 testing and administer vaccines—a move that has resulted in more than 152.7 million COVID-19 vaccine doses administered by retail pharmacies across the United States. ¹

“Without the leveraging of community pharmacies as access points for care, many Americans would not have been vaccinated or had easy access to COVID-19 testing,” Clark said.

Although the pandemic has certainly come with its share of challenges, Clark also sees the opportunities that have come from COVID-19—in particular, the importance of empowering pharmacists to practice at the top of their license.

“More people are now seeing how absolutely powerful and necessary a pharmacist practicing at the top of their license is to local and national health,” she said. “The more we as pharmacists test and treat, the more opportunities will come for additional scope expansion.”

As the opportunities come, though, pharmacists will need to abandon “patched together” scheduling and reporting systems, Clark noted. “The volume of services now being booked—as well as the requisite scheduling and reporting—are too much to do by hand,” she said. Technology can streamline these processes and allow pharmacists to focus on patient care, but deciding which technology to use—and then implementing and using it—often creates another roadblock for community pharmacists to face.

Enter MyRx PRO, a secure, comprehensive pharmacy management platform built by pharmacists, for pharmacists. “After years of working as pharmacists, our team at Prescriptive has focused on one thing: making a comprehensive system that works for pharmacists practicing today,” Clark explained. “This platform helps pharmacists launch new clinical services, connect with new patients, and optimize the pharmacy workflow.” Pharmacists will also see time savings in patient information collection, scheduling, reporting, and billing.

MyRx PRO also features SmartPRICE, a cash solution that lets pharmacists serve more customers while improving their bottom line. SmartPRICE uses artificial intelligence to optimize pricing, connects new customers to pharmacies via Prescriptve’s health intelligence platform, and has low, transparent administrative fees. “Altogether, this means more profit to pharmacies and more competitive pricing for patients—as much as 80% savings on prescription drugs,” Clark said.

For patients, MyRx PRO includes MyRx.io, a patient-friendly mobile experience that connects pharmacists and patients. Patients are empowered to search for clinical services, find an available pharmacy near them, and schedule an appointment, as well as prefill questionnaires and make payments—all before walking through the pharmacy door.

“There’s an important bond between community pharmacists and their patients,” Clark said. “People in the United States rank pharmacists as one of their most trusted health care providers. For the majority of us, this trust and our relationship with patients are what make our jobs fulfilling.

“COVID-19 blew open the door to scope expansion, and now we all need to walk through it,” she added. “Prescriptve is a champion of the community pharmacist and is excited to work together to build a stronger future for pharmacy.”

REFERENCE
In the Era of Virtual Care, Tech Tools Facilitate Patient-Provider Engagement

Mobile apps and fitness trackers predate the COVID-19 pandemic but are being utilized more ever before. By Karen Appold

From home health monitoring devices to fitness tracking wearables, technology use in health care settings has significantly increased since the onset of the COVID-19 pandemic. Because the pandemic necessitated a switch to virtual care, patients and providers alike embraced digital tools—like those that facilitate at-home self-monitoring, improve medication adherence, or help manage lifestyle habits like diet and exercise.

“Pharmacists can guide patients on the most appropriate tech tools to use based on patient-specific factors to ensure optimal management of their medical conditions,” said Briann Fischetti, PharmD, MBA, BCACP, AAHIVP, an associate professor of pharmacy practice at The Arnold & Marie Schwartz College of Pharmacy and Health Sciences (LIU Pharmacy) at Long Island University in Brooklyn, New York.

Electronic Health Record Platforms

Patients can use portals like Epic’s MyChart on their phone or computer, putting a tremendous amount of health information at their fingertips. They can schedule appointments, receive test results, manage prescriptions, and review medical records.

“I encourage every patient, even if they’re not comfortable with technology, to try out their health care providers’ patient portal. It’s a great way to engage with their care team and be an active part of their health care,” said Elizabeth Hall, PharmD, informatics pharmacist in outpatient pharmacy, The Ohio State University Wexner Medical Center, Columbus, Ohio.

Brooke Fidler, PharmD, associate professor of pharmacy practice at Long Island University’s LIU Pharmacy, is also a proponent of MyChart. “Many health systems use Epic as their electronic medical record system. It’s one of the more user-friendly portals,” she said. “[It] allows patients to message their provider for medication-related questions or refills.”

Mobile Apps

Hundreds of phone applications are geared toward monitoring medication adherence and managing chronic diseases like diabetes. “I recommend discussing a patient’s wants and needs for an application while also considering how technologically savvy they are,” said Maria Sorbera, PharmD, AAHIVP, BCACP, assistant professor of pharmacy practice at Long Island University’s LIU Pharmacy.

Many applications are free or have tiered access. These applications are also great tools to assist motivated patients with improving their medication adherence and disease control, Sorbera added. In many cases, an app can also serve as a medication list for patients to bring to new providers or to refer to if they’re hospitalized.

Medisafe helps users organize

CONSIDERATIONS WHEN RECOMMENDING A TECHNOLOGY TOOL

Before recommending a technology tool to a patient, consider the following factors:

1. Health literacy: Patients who aren’t health literate may struggle with complex tracking apps.

2. Tech savviness: A patient who doesn’t own a smartphone isn’t a good candidate for a mobile calorie tracking app like MyFitnessPal.

3. Insurance issues: Some insurance companies present challenges when patients or providers try to access at-home health monitoring tools.

4. Financial means: Avoid suggesting subscription-based apps to patients who don’t have the financial means to purchase them.
medications and improve medication adherence. Users can enter all their medications, including the drug name, dosage, frequency, and indication, and set up reminders to take medication at certain times each day. The Medifriend feature allows users to sync their app with that of a family member, letting others stay informed in case a dose is missed, according to Amanda Phoenix, PharmD, BCACP, CDE, an assistant professor of pharmacy practice at Touro College of Pharmacy and ambulatory care clinical pharmacist at BronxCare Health System in New York, New York.

MyFitnessPal can provide customized health plans based on individual user health goals, sex, age, and weight. Users can enter the foods they eat each day, then track calorie intake against a daily allowance, Phoenix explained. This app uses the smartphone accelerometer to track steps and provides helpful workout and meal-prep tips.

CalorieKing is for those who want to watch what they eat. Users can check nutrition labels and find the calories, carbohydrates, sugars, fat, sodium, and protein per serving. “This app is ideal for patients who count carbs for diabetes management or for people who count calories to help lose weight,” Phoenix said.

For patients with type 2 diabetes, BlueStar allows providers to access patient health information remotely. Users can manually add their blood glucose and message providers with questions if their blood glucose is out of range.

“This is a great tool for patients who require touch points between visits and appreciate a collaborative approach to their care,” Fischetti said.

Notifications and Reminders

The simplest way to track medication reminders is by setting an alarm or calendar notification using the apps on a mobile phone.

“This can be a good option for patients with poor health literacy or for (older) patients who aren’t technologically savvy,” Fidler said. A daily alarm can also be set on most glucometers to remind patients to check their glucose. For those more comfortable with technology, some free phone apps give reminders for medication refills and medication dosing at a prescheduled time. Pill Reminder and MyTherapy can also be used to remind patients to take medications.

Messaging-based Platforms

Messaging-based platforms provide ways for pharmacies and other health care providers to communicate with their patients.

“We encourage patients to take advantage of these messaging systems because sometimes it can be difficult to contact a health care provider by phone,” Sorbera said. Most of these platforms require a pharmacy or clinic to pay for the service but are usually free to patients.

Klara is an all-in-one platform that allows patients to communicate with health care providers. Communications sent to patients are received as text messages with a confidential link that, when clicked, brings the patient to the messaging portal; patients don’t have to download an application. MyChart also includes a messaging component for patients to contact providers, make appointments, and request medication refills.

Health Tracking Monitors

For motivated patients, wearable monitors can be a great adjunct to medication therapy and can assist with lifestyle modifications, Fischetti said. Basic health tracking tools include fitness-specific wearables like Fitbit and more general devices like the Apple Watch. These wearable fitness trackers can help patients set realistic goals.

“You can ask patients to track their activity for 1 or 2 weeks [and] then review their baseline activity,” Fischetti said. “From there, goals for the number of steps, calories burnt, and so forth can be set and monitored. Monitors also assist with accountability because patients know that we’ll review trackers when we meet.”

Social Media

In general, Fidler doesn’t recommend social media sites to patients.

“Due to the abundance of medical and medication misinformation on social media platforms, I have found that it’s best to avoid steering patients to social media for medication management,” she said. “Patients may want to independently use social media for support groups and social support; however, I may caution them to ask their health care provider before implementing (the) recommendations discovered on social media.”

Pharmacists can direct patients who are looking for updates—or notifications on specific medical-related issues in the news—to reputable social media sources, Sorbera said. For example, pharmacists can direct patients who want current information on COVID-19 to the CDC’s social media pages.

Advising Patients

Patients should ask their health care providers for suggestions before committing to any paid application subscriptions, Fischetti noted. “It may be tempting to have advanced features, but many patients may not need these features and it’s best to learn how to navigate an application prior to buying a subscription,” she said.

The most important factors to consider before recommending one of these tools is the patient’s level of health literacy, how tech savvy they are, their insurance situation, and their financial means.

“Unfortunately, insurers can hinder the use of many advanced tools for home monitoring,” Fidler said. “However...a number of free applications and simple tools [are available] to aid in medication adherence and disease state management.”

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Cannabis Consulting: Are You Ready?

Most pharmacists are moderately to not-at-all comfortable answering patient questions about cannabis. That needs to change. 

by Gabrielle Ientile

When it comes to cannabinoids, some pharmacists find themselves on shaky ground: according to Jeffrey Stewart, RPh, 78% of pharmacists are uncomfortable answering patient questions about CBD, and 76% didn’t know that CBD is just an abbreviation for cannabidiol.

Stewart—co-founder and managing partner of Pharmtrue—shared these statistics during his “Cannabis Crash Course” session at the 2021 Total Pharmacy Solutions Summit.

When Stewart dove into the cannabis industry 3 years ago, he realized that his education had failed to prepare him for patient questions about cannabis use. When he sought out quality resources, he again came up short. “It took years navigating the cannabis industry and countless hours on PubMed, sifting through case reports, case series, looking at the interactions, for me to get to the point where I felt comfortable enough to discuss [cannabis use] with my patients,” Stewart said.

Not wanting that research to go to waste, Stewart applied his newfound knowledge to Pharmtrue, which has now coached 500 pharmacists, pharmacy technicians, students, and pharmacy staff on effective, approachable methods that can be used to discuss cannabis use with patients—all in less than 6 months.

Teach Patients the Basics

Even the most basic information about cannabis can be confusing to patients. Stewart likened hemp and marijuana to lemons and limes—a comparison that may be helpful to keep in mind when consulting patients.

“Just like lemons and limes fall under this larger classification of citrus, a genus of flowering trees, hemp and marijuana fall into this larger classification of cannabis, a genus of flowering plants,” Stewart explained.

Hemp and marijuana can both produce CBD and tetrahydrocannabinol (THC), and the 2018 Farm Bill defined the difference between the two as the threshold of THC concentration,” Stewart said. Hemp has a ∆-9-THC concentration of less than 0.3% by dry weight, whereas marijuana has a ∆-9-THC concentration of more than 0.3%.

Although hemp was legalized through the 2018 Farm Bill, marijuana remains a Drug Enforcement Agency Schedule I controlled substance, approved only for medical use in 33 states.

Build Confidence in Consulting

Pharmacists are already equipped with the fundamental knowledge needed to understand the endocannabinoid system, including the 3 main classifications of cannabinoids—phytocannabinoids, endocannabinoids, and synthetic cannabinoids—all of which interact differently in the body.

Cannabinoids interact with the body through CB1 and CB2 receptors. CB1 is the most abundant G-protein–coupled receptor in the mammalian brain, located along presynaptic neurons in the brain, spinal cord, and peripheral nervous system. CB2 receptors are primarily located in immune cells and tissues, Stewart explained.

Looking at SSRIs Stewart used the example of SSRIs to illustrate how cannabinoids interact in the body. Just as fluoxetine inhibits reuptake of serotonin to allow more serotonin to remain in the brain for longer periods of time, CBD inhibits reuptake of anandamide—which produces similar effects to serotonin—allowing it to produce more of an effect.

Questions to Expect

Patients are often concerned about whether CBD will make them feel “high” or fail a drug test. According to Stewart, the answer depends on the type of CBD patients are consuming.

The pure molecule of CBD won’t create a psychoactive effect and won’t affect drug test results, but pharmacists need to keep in mind how CBD will be delivered to patients. Tinctures, capsules, and gummies can fall into 3 categories: broad-spectrum products include various cannabinoids but excludes THC, while full-spectrum products may cause psychoactive effects or patients to exceed the THC threshold of a drug test if they take a large enough dose. Isolate products only include CBD.

Industry trends seem to point to a bright future for medical cannabis: 68% of US adults support the legalization of marijuana, and 16% are already using cannabis daily, according to Stewart.

“As health care providers, we believe that we have to be ready to answer all those questions that we’re sure to get,” Stewart said. “We’re in the perfect position to help out patients, and we’re also in the perfect position to hurt them.”

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The COVID-19 pandemic has brought many changes to the pharmacy profession. Because pharmacists are one of the most accessible health care professionals, they play an integral role in patient care management. From pediatric COVID-19 vaccines to the first interchangeable biosimilar products, multiple innovations have changed—and advanced—the pharmacy profession this year, and it is critical for pharmacists to stay up-to-date on these developments.

**Advances in COVID-19**

On August 23, the FDA approved the Pfizer-BioNTech COVID-19 messenger RNA vaccine (Comirnaty) for the prevention of COVID-19 disease in individuals 16 years and older. This is the first FDA approved COVID-19 vaccine, with approval based on positive efficacy and safety data in patients 6 months after the administration of a second dose.1

In another recent milestone, the FDA granted emergency use authorization on October 29 for the Pfizer-BioNTech COVID-19 vaccine in children aged 5 to 11 years, with CDC approval following closely on November 2.2,3 Pharmacists are now playing an integral role in vaccinating children across the country, as well as educating vaccine-hesitant parents in an effort to increase immunization rates.

In addition, the US Department of Health & Human Services announced an amendment to the COVID-19 Public Readiness and Emergency Preparedness (PREP) Act to allow licensed pharmacists, pharmacy technicians, and pharmacy interns to order and administer select COVID-19 therapeutics for subcutaneous, intramuscular, or oral administration.4 As part of the PREP Act amendment, an approved training program for subcutaneous and intramuscular injections should include hands-on injection technique, clinical evaluation of indications and contraindications of COVID-19 therapeutics, and possible treatment-related adverse reactions.4

**Interchangeable Biosimilar Products**

Two interchangeable biosimilar products received FDA approval in 2021: insulin glargine-yfgn (Semglee) and adalimumab-adbm (Cyltezo).5,6 Interchangeable biosimilars have separate, additional regulatory designations and must undergo additional clinical research to demonstrate that they produce the same clinical result as their reference product. Only then may interchangeable biosimilars be substituted for the reference product at the pharmacy, which can help increase patient access to these medications.

The reference-listed product for insulin glargine-yfgn is insulin glargine (Lantus), a long-acting insulin. Insulin glargine-yfgn is approved for the treatment of type 1 diabetes in children and adults and type 2 diabetes in adults.3 This interchangeable biosimilar approval will help make insulin more affordable for patients as insulin prices have skyrocketed.

Adalimumab-adbm is the first interchangeable biosimilar to adalimumab (Humira) for the treatment of multiple inflammatory diseases,4 including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn disease, ulcerative colitis, and chronic plaque psoriasis.

**New Naloxone Products for Opioid Overdose Prevention**

According to the CDC, more than 96,000 drug overdose deaths occurred between March 2020 and March 2021, indicating an increase during the COVID-19 pandemic.3 Pharmacists play a critical role in ensuring patients have access naloxone for opioid overdose reversal.

Two new naloxone products were approved this year. Naloxone HCl (Kloxxado) is a higher-dose naloxone nasal spray that delivers 8 mg of naloxone—twice as much as naloxone HCl (Narcan Nasal Spray)7—and naloxone hydrochloride (Zimhi), administered via a single-dose, prefilled syringe that delivers 5 mg of naloxone as an intramuscular or subcutaneous injection.8 These approvals both provide additional options for the treatment of opioid overdoses.

For references, visit drugtopics.com.

Jennifer Gershman, PharmD, CPh is a drug information pharmacist and medical writer residing in South Florida.
Profits Soar, But Pay Stays the Same: Chain Pharmacists Are Ready to Speak Up

By Peter A. Kreckel, RPh

Last month I discussed pizza and the hashtag floating around social media—#PizzaIsNotWorking—that reflects the ways in which management needs to address salaries to help retain pharmacy technicians.

I use social media infrequently—typically to read posts about pharmacy or my former student’s achievements and to keep up with extended family. I don’t have a Twitter account and am clueless about Snapchat. But if I did have a Twitter account, I’d start the hashtag to the effect of #PharmacistsAreNotScaredAnymore.

I am seeing a true revolution in this profession, especially in my observations of chain pharmacists. One year ago, my fellow pharmacists would refer to WalMart, Walgreens, and CVS as “Spark,” “Corner,” and “3-Letter,” respectively, to make it more difficult for regional managers to monitor derogatory comments. Now, however, pharmacists openly and blatantly criticize their managers, their staffing levels, and their salaries. Pharmacists are not scared anymore!

I am seeing pharmacists inundated with COVID-19 and flu shot administration with no increase in either help or salary, are mad as hell and not taking it anymore. Pharmacists apply for residencies to position themselves for a job that is not community-pharmacy related. Many of the students I interact with have not only a lack of interest in practicing community pharmacy, but also a real disdain for this area of practice. It’s too bad, because there is not a health care professional anywhere who can have a more direct influence on patient care—if working conditions allow for it. The level of practice most community pharmacists wish to attain can only be attained through sufficient staffing, competent pharmacists, and salaries that are adequate.

Pharmacists should be doing patient care, not typing on computers, running cash registers, or counting pills. Any of those tasks can be easily accomplished by a technician. Pharmacists should be doing patient care. Instead, community pharmacists are leaving this profession in droves.

When I took my Boy Scout troop camping, I would tell them to leave the environment better than they found it. Such is not the case in this profession: Pharmacists have had enough and are letting the world know that pizza is not working and that pharmacists are not scared anymore. =

For references, visit drugtopics.com.

Peter A. Kreckel, RPh, practices community pharmacy in Lemont Furnace, Pennsylvania.
As the COVID-19 pandemic drags on, the pharmaceutical industry continues to face uncertainty regarding the stability and quality of the drug supply chain. The American Society of Health-System Pharmacists (ASHP) provided both insight into and recommendations on how to combat supply chain issues in its 2021 ASHP Foundation Pharmacy Forecast. Now—nearly a year later—the report’s authors and other experts have come together to discuss what progress has been made to address supply chain issues.

Allocating Scarce Resources

Of the 272 forecast panelists surveyed, 90% thought that at least 75% of health systems would develop guidelines through ethics committees or similar processes to allocate finite resources during a disease pandemic. Although Erin R. Fox, PharmD, senior pharmacy director at University of Utah Health in Salt Lake City and an author of the ASHP report, said there isn’t a tracking mechanism to determine how many health systems have developed allocation guidance, the Centers for Medicare & Medicaid Services requires that all hospitals have policies in place regarding drug shortages. “The pandemic forced most hospitals to develop strategies for using limited resources,” said Fox. For example, when remdesivir (Veklury) first became available through an FDA emergency use authorization (EUA), no hospital received the amount it needed to treat all patients who could qualify under that EUA.

Paige Clark, RPh, vice president of pharmacy programs and policy at Prescriptiv Health, Inc in Redmond, Washington, said that health care systems have been preparing for a COVID-19 scenario since 2009 when the influenza A virus emerged globally. These preparations, she noted, were made with the understanding that an influx of infected patients would strain all parts of the health care ecosystem. But even with these preparations in place, COVID-19—more specifically, the Delta variant surge in July and August—considerably strained numerous health systems, including those in Florida, Oregon, and Texas.

From a national perspective, Michael Ganio, PharmD, MS, BCPS, FASHP, senior director of pharmacy practice and quality at ASHP in Bethesda, Maryland, said that the federal government, medical corporations, and other organizations have been able to identify vulnerabilities in the supply chain and the ability of the United States health care system to respond to emergencies.

“Since the start of the pandemic, both [the] public and private sectors have taken steps to address vulnerabilities—such as addressing limitations of the strategic national stockpile or building more redundancy in supply chains—which should improve our nation’s ability to maintain access to necessary supplies and medications,” he said.

Medication Quality and Supply

One key recommendation from a recent report by the FDA’s Drug Shortages Task Force was to develop a manufacturing quality rating system to provide incentives for drug manufacturers to invest in improving their facilities. Forecast panelists were almost evenly split on whether this would come to fruition.

According to Fox, the FDA has recommended a ratings system since 2013 when Janet Woodcock, who headed the FDA’s pharmaceutical division at that time, first wrote how such a system could improve quality and shortages. However, the FDA has yet to implement a ratings system, and the private sector cannot implement one without the necessary transparency. For example, pharmaceutical companies aren’t required to disclose the name of the company that made a particular product or the factory in which it was made. “Unless the United States Congress requires improved transparency from pharmaceutical companies, I don’t think the FDA will create a ratings system,” Fox said.
The ASHP report mentioned that congressional representatives have introduced multiple bills related to moving drug manufacturing back to the United States, but, Ganio said, there has not been much movement on these bills. There have, however, been executive orders from both current and previous administrations to increase domestic manufacturing. Similarly, the Biomedical Advanced Research and Development Authority, a division of the US Department of Health & Human Services, has made investments in increasing domestic production of some essential medications and their active ingredients.

But according to Ganio, moving drug manufacturing back to the United States alone is not a solution. “There are still some raw materials and precursor chemicals that are not made domestically,” he said. “The domestic pharmaceutical supply chain is also vulnerable to disruption, as we experienced with small-volume saline bags after Hurricane Maria in September 2017.

“Although these products are manufactured domestically, there were still severe, critical shortages of essential medications. Investments in supply chain resiliency, including redundancy and in new manufacturing technologies that can quickly scale up production, are also important strategies to ensure the Unites States maintains access to essential medications during an emergency.”

Importing Drugs

Regarding international markets as a source of lower drug pricing, most pharmacy panelists (68%) expected the United States to adopt rules to import prescription drugs from other countries as a way to help lower drug prices.

“Importation of prescription drugs has been proposed for decades, but prior presidential administrations were reluctant to push for more vigorous implementation of importation in the face of opposition by the pharmaceutical industry,” wrote the authors of the ASHP report. “While importation of single-source brand-name drugs may not be feasible, FDA may develop pathways for responding to generic drug shortages (or price hikes) by facilitating the regulatory approval of overseas manufacturers of those products.”

Both the current and previous administrations have included importation in their plans to lower prescription drug prices, but progress has been slow, Ganio said, and there are some concerns with these potential plans.

Ganio noted that importation may conflict with attempts to guarantee the pedigree of prescription drugs that are required in the FDA’s Drug Supply Chain Security Act. Importation also requires a willingness of manufacturers and wholesalers to sell products from Canada to the United States; however, Canada—concerned with ensuring its own supply of medications—has repeatedly signaled that it may move to block the export of pharmaceuticals if the United States implements a drug importation program.

According to Clark, multiple factors need to be in place for the successful import of prescription drugs, including quality control and the supply chain to ensure the safety of United States citizens. “The process would need to have measures in place to ensure that drugs are made to US quality standards. The US has extremely stringent standards to protect the safety of its citizens,” she said. “Similarly, all aspects of the supply chain must be monitored so that there aren’t any delays, breakdowns, or any other activity that could compromise the security, quality, and delivery of drugs to the US.”

Other Solutions

New manufacturing technologies can help improve the quality and reliability of pharmaceutical manufacturing, Ganio said. Continuous manufacturing is more agile than traditional batch manufacturing and can quickly scale up production in response to demand or shift production from one medication to another. “This type of scalable end-to-end manufacturing is a promising advancement in pharmaceutical manufacturing, but it’s expensive to adopt and will take years to implement,” he said.

Joseph T. DiPiro, PharmD, dean of the School of Pharmacy, Archie O. McCalley Chair and associate vice president for health sciences, faculty affairs, at Virginia Commonwealth University in Richmond, who is also an author of the ASHP report, noted that the United States has taken steps to develop a more secure domestic supply chain for generic drugs. In May 2020, the federal government allocated $354 million to build a national stockpile of essential medications. Plow Corp, a new company in Richmond, Virginia, is working with Civica Rx in Petersburg, Virginia, and AMBAC Fine Chemicals in Las Vegas, Nevada, on this effort.

Outlook for 2022

According to Ganio, the prescription drug supply chain outlook for 2022 is anticipated to be the same as in 2021. “There are very big issues to address, and solutions will not be implemented overnight,” he said. “Barring any worsening of the pandemic or other geopolitical challenges or natural disasters, we will continue to manage drug shortages that mostly occur as a result of quality problems in manufacturing facilities.”

Recent escalation in shipping issues at ports and with trucking companies is alarming and also a threat to drug supply chains. “Trade restrictions, pandemics, and climate change continue to threaten the drug supply chain, posing an increased potential for drug shortages, and its future impact is unknown,” DiPiro said.

The 2022 ASHP Foundation Pharmacy Forecast is scheduled to publish in early December.

For references, visit drugtopics.com.
FDA Approves Atogepant for Preventive Treatment of Episodic Migraine

Madeleine DePinho, BS, PharmD Candidate 2022; Cassandra R. Doyno, PharmD, BCPS, BCCCP

On September 28, the FDA granted approval to oral atogepant (Qulipta) for the prevention of migraine. Migraine is a debilitating headache disorder, categorized as either episodic (0-14 headache days per month) or chronic (15 or more headache days per month).

Calcitonin gene-related peptide (CGRP) has been linked to migraine pathophysiology and remains a target for migraine therapy development. Previous therapies targeting the CGRP receptor or ligand have been approved for both prevention and treatment of migraine. Prior to the approval of atogepant, the only available preventative therapy targeting CGRP was injectable. Atogepant is the first oral preventative migraine therapy of its class.

Investigators for the phase 3 ADVANCE trial (NCT03777059) evaluated the efficacy of once-daily oral atogepant (10-mg, 30-mg, and 60-mg doses) in adults with episodic migraine. Initial efficacy results from a phase 2b/3 dose-ranging study (n = 834) determined that the drug was safe and well tolerated.

In ADVANCE, patients were randomly assigned 1:1:1:1 to evaluate once-daily atogepant 10 mg (n = 221), 30 mg (n = 228), 60 mg (n = 231), or placebo (n = 222). A modified ITT population was included in the efficacy analysis (n = 873). All doses were effective in reducing the number of migraine days per month over a 12-week period vs placebo. Atogepant reduced migraine days by 3.7 to 4.2 days per month. Mean differences from placebo in reduction of migraine days per month were 1.2 to 1.7 days per month across all doses (10 mg: –1.2 days; 95% CI, –1.8 to –0.6; 30 mg: –1.4 days; 95% CI, –1.9 to –0.8; 60 mg: –1.7 days; 95% CI, –2.3 to –1.2; P < .001 for all). Differences from placebo were observed within the first 4 weeks following treatment initiation and were maintained during subsequent 4-week intervals over the total 12 week study period.

Safety and tolerability data come from 2 randomized, controlled, double-blind trials. In the phase 3 trial, safety laboratory assessments were required, at minimum, every 8 weeks. The most common emergent adverse events were nausea (60-mg dose, 6.1%), constipation (10-mg dose, 7.7%), and upper respiratory tract infections (30-mg dose, 5.7%). Incidence of constipation was higher in the atogepant group (7.7%) than the placebo group (0.5%). Serious adverse events included 1 case of asthma and 1 case of optic neuritis in the 10-mg group. Safety assessments included pregnancy testing, Columbia Suicide Severity Rating Scale evaluation, and concomitant medications. Twenty-five patients discontinued therapy due to adverse events.

Recommended atogepant dosing is 10-mg, 30-mg, or 60-mg tablets once daily for patients with a history of episodic migraine. The safety of atogepant was not evaluated in pregnant women in the phase 3 trial. There were minimal cases of asymptomatic transaminase elevations (identified as greater than 3 times the upper limit of normal) temporarily associated with atogepant treatment. Although elevations resolved in 8 weeks following discontinuation, atogepant should be avoided in patients with severe hepatic impairment. Recommended atogepant dose with strong cytochrome P450 3A4 inhibitors such as ketoconazole or itraconazole is 10 mg once daily, as concomitant use slows clearance of the drug. When using atogepant with strong cytochrome P450 3A4 inducers such as rifampin or carbamazepine, increase the dose to 30 mg or 60 mg once daily, due to increased clearance of atogepant. For organic anion transporting polypeptide inhibitors, 10-mg or 30-mg once-daily atogepant should be used. Patients with a creatinine clearance less than 30 mL/min should receive a dose of 10 mg by mouth once daily.
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BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)
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 (HZ) (shingles) in adults aged 50 years and older.

Limitations of Use:
• SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE 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 2 to 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.

5.2 Guillain-Barré Syndrome (GBS)
In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

5.3 Syncope
Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

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 another vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Adults Aged ≥50 Years and Older
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 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 50 to 59 years, and 17,531 (60%) 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%), followed by Asian (18%), Black (1.4%), and other racial/ethnic groups (8%); 58% were female.

Solicited Adverse Reactions: In Studies 1 and 2, data on solicited local and general adverse reactions 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 and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%), redness (38%), and swelling (26%); and myalgia (45%), fatigue (46%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

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

Table 1. Percentage of Subjects with Solicited Local and General Adverse Reactions within 7 Days of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older (Total Vaccinated Cohort with 7-Day Diary Card)

<table>
<thead>
<tr>
<th>Adverse Reactions</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></td>
<td>n=1,315 %</td>
<td>n=1,312 %</td>
<td>n=1,311 %</td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>11</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Redness</td>
<td>39</td>
<td>1</td>
<td>38</td>
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<td>Redness, &gt;100 mm</td>
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<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Swelling</td>
<td>31</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>General Adverse Reactions</td>
<td>n=1,315 %</td>
<td>n=1,312 %</td>
<td>n=1,305 %</td>
</tr>
<tr>
<td>Myalgia</td>
<td>57</td>
<td>15</td>
<td>49</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>9</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57</td>
<td>20</td>
<td>46</td>
</tr>
<tr>
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<td>9</td>
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<td>5</td>
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<tr>
<td>Headache</td>
<td>51</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
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<tr>
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<tr>
<td>Shivering, Grade 3</td>
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<td>0.2</td>
<td>5</td>
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<tr>
<td>Fever</td>
<td>28</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0.4</td>
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</tr>
<tr>
<td>GI</td>
<td>24</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>GI, Grade 3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

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

1 7 days included day of vaccination and the subsequent 6 days.
2 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.
3 Placebo was a saline solution.
4 Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.
5 Grade 3 myalgia, fatigue, headache, shivering, and GI: Defined as preventing normal activity.
6 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.
7 GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.
8 The incidence of solicited local and general reactions was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

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

(continued on next page)
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% and 21%, respectively) compared with Dose 1 (24% and 14%). In the last 2 solicited local reactions (headache, shivering, myalgia, and fatigue), there were no differences in proportions of subjects reporting reactions between Dose 2 (22.3%, 3%, 4%, and 4%, 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 51% and 32% of subjects who received SHINGRIX (n = 14,645) or 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 (4% versus 0.2%), injection site pruritus (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 or 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%) or placebo (2.2%) from the first administered dose up to 30 days post-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 39°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 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 2 hours. A causal relationship to the vaccine cannot be ruled out.

Nervous System Disorders
Guillain-Barré syndrome.

Hypersensitivity reactions, including angioedema, rash, and urticaria.

Potential Immune-Mediated Diseases: In the 2 studies, new onset 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.

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HOW IMPORTANT IS IT TO COMPLETE THE 2-DOSE SERIES?

VERY IMPORTANT

MAKE SURE YOU ADMINISTER A SECOND DOSE OF SHINGRIX 2-6 MONTHS AFTER THE FIRST.

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
• In a postmarketing observational study, an increased risk of Guillain–Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
• Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope

Important Safety Information (cont’d)
• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• 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
• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Reference: Prescribing Information for SHINGRIX.

Please see Brief Summary of Prescribing Information for SHINGRIX on the previous pages.

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Steven M. RPh, Texas

“Dan was able to negotiate a much higher price for my pharmacy than I would have been able to get on my own. Dan was on-site to guide me during the actual sale and help me through the transition. I don’t know what I would have done without having him in my corner.”

Jim C. RPh, Missouri

“I am a practicing attorney in California representing numerous business owners. Recently one of my clients decided to sell his pharmacy. I retained Dan Lannon to locate the prospective buyer, negotiate the terms of the sale, and to consummate the transaction. He did it all and in a very professional manner. Thanks Dan.”

Brad F., Attorney, California
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