ACCESS MATTERS

CARE INEQUITY AND MINORITY POPULATIONS

TECHNOLOGY
Invest in Telepharmacy

CAREERS
Pharmacists and Public Health

PAIN
OTC For Oral Pain

TOTAL PHARMACY
Marketing on Social Media
Choose VAXNEUVANCE to help protect adults in your pharmacy who are at increased risk for IPD.

Indications and Usage

VAXNEUVANCE is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older.

Serotype 3

Invasive pneumococcal disease (IPD) is an infection caused by different bacterial strains or "serotypes." Over the last decade, serotype 3 has been a significant cause of IPD in adults. In fact, serotype 3 is the leading cause of IPD in the US.

-~15%~
of IPD cases in adults in the US are caused by serotype 3.

That's about 1 in 6 cases.

VAXNEUVANCE can help protect your appropriate adult patients against IPD caused by serotype 3.

Select Safety Information

Do not administer VAXNEUVANCE to individuals with a severe allergic reaction (eg, anaphylaxis) to any component of VAXNEUVANCE or to diphtheria toxoid.

Some individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to VAXNEUVANCE.

The most commonly reported solicited adverse reactions in individuals 18 through 49 years of age were: injection-site pain (75.8%), fatigue (34.3%), myalgia (28.8%), headache (26.5%), injection-site swelling (21.7%), injection-site erythema (15.1%), and arthralgia (12.7%).
In fact, serotype 3 is the leading cause of IPD in the US. 3

"serotypes."1

Invasive pneumococcal disease (IPD) is an infection caused by different bacterial strains or

by

Streptococcus pneumoniae
VAXNEUVANCE is indicated for active immunization for the prevention of invasive disease caused

Indications and Usage

in adults 18 years of age and older.

IPD caused by serotype 3.
VAXNEUVANCE can help protect your appropriate adult patients against

Select Safety Information (continued)
The most commonly reported solicited adverse reactions in individuals 50 years of age and older were: injection-site pain (66.8%), myalgia (26.9%), fatigue (21.5%), headache (18.9%), injection-site swelling (15.4%), injection-site erythema (10.9%), and arthralgia (7.7%).
Vaccination with VAXNEUVANCE may not protect all vaccine recipients.

Randomized controlled trials assessing the clinical efficacy of VAXNEUVANCE compared to PCV13 have not been conducted.
PCV13, 13-valent pneumococcal conjugate vaccine.

References:
ADVERSE REACTIONS

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most commonly reported solicited adverse reactions in individuals 18 through 49 years of age and older were: injection-site pain (66.8%), myalgia (29.1%), headache (26.5%), injection-site swelling (21.7%), injection-site erythema (15.1%) and arthralgia (12.7%).

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Safety Assessment in Clinical Studies

The safety of VAXNEUVANCE was assessed in 7 randomized, double-blind clinical studies conducted in the Americas, Europe and Asia Pacific, in which 5,630 adults 18 years of age and older received VAXNEUVANCE and 1,808 adults received Prevnar 13 (Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM® Protein)). In Studies 1-3 (NCT03395062, NCT03395085, and NCT03480763), a total of 3,032 adults 50 years of age and older with no history of pneumococcal vaccination received VAXNEUVANCE and 1,154 participants received Prevnar 13 in Study 4 (NCT03547167), adults 18 through 49 years of age with no history of pneumococcal vaccination, including individuals with increased risk of developing risk of pneumococcal disease, received VAXNEUVANCE (N=1,134) or Prevnar 13 (N=378), followed by PNEUMOVAX 23 six months later. In Study 5 (NCT02573181), adults 65 years of age and older previously vaccinated with PNEUMOVAX 23 (at least 1 year prior to study entry) received VAXNEUVANCE (N=127) or Prevnar 13 (N=126). In Study 6 (NCT03615482), adults 50 years of age and older received VAXNEUVANCE concomitantly with a seasonal inactivated quadrivalent influenza vaccine (Fluarix Quadrivalent, QIV (Group 1, N=600) or nonconcomitantly 30 days after QIV (Group 2, N=585). In this study population, 20.9% of individuals had a history of prior vaccination with PNEUMOVAX 23. In Study 7 (NCT03480802), HIV-infected adults 18 years of age and older received VAXNEUVANCE (N=152) or Prevnar 13 (N=150), followed by PNEUMOVAX 23 two months later.

The clinical studies included adults with stable underlying medical conditions (e.g., diabetes mellitus, renal disorders, chronic heart disease, chronic liver disease, chronic lung disease including asthma) and/or behavioral risk factors (e.g., smoking, increased alcohol use) that are known to increase the risk of pneumococcal disease. Overall, the mean age of the participants was 58 years and 54.6% were female. The racial distribution was as follows: 72.3% were White, 9.9% were Asian, 8.1% were American Indian or Alaska Native, 7.4% were Black or African American, and 18% were of Hispanic or Latino ethnicity.

In all studies, safety was monitored using a Vaccination Report Card (VRC) for up to 14 days postvaccination. Study investigators reviewed the VRC with the participants 15 days postvaccination to ensure consistency with protocol definitions. The analyses presented in Tables 1-3 reflect the information based on the final assessment by the study investigators. Oral body temperature and injection-site adverse reactions were solicited on Day 1 through Day 5 post vaccination.

Systemic adverse reactions were solicited on Day 1 through Day 14 post vaccination. Unsolicited adverse events were reported on Day 1 through Day 14 post vaccination. The duration of the safety follow-up period for serious adverse events post vaccination with VAXNEUVANCE was 1 month in Study 5; 2 months in Study 7; 6 months in Studies 1, 2, 4 and 6; and 12 months in Study 3.

Solicited Adverse Reactions

The percentage of participants with solicited adverse reactions that occurred within 5 or 14 days following administration of VAXNEUVANCE or Prevnar 13 in 3 studies are shown in Tables 1-3. The majority of solicited adverse reactions lasted ≤3 days.

Table 1: Percentage of Participants with Solicited Local and Systemic Adverse Reactions in Pneumococcal Vaccine-Naïve Adults 50 Years of Age and Older (Study 3)*

<table>
<thead>
<tr>
<th></th>
<th>VAXNEUVANCE (%)</th>
<th>Prevnar 13 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=2,103</td>
<td>N=2,310</td>
</tr>
</tbody>
</table>

**Local Reactions***

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE Any</th>
<th>Grade 3†</th>
<th>Prevnar 13 Any</th>
<th>Grade 3†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>66.8</td>
<td>0.9</td>
<td>52.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Headache</td>
<td>18.9</td>
<td>0.7</td>
<td>22.2</td>
<td>0.9</td>
</tr>
<tr>
<td>Myalgia</td>
<td>26.9</td>
<td>0.4</td>
<td>21.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>7.7</td>
<td>0.2</td>
<td>5.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Fever‡</td>
<td>0.6</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Systemic Reactions‡**

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE Any</th>
<th>Grade 3†</th>
<th>Prevnar 13 Any</th>
<th>Grade 3†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>66.8</td>
<td>0.9</td>
<td>52.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Headache</td>
<td>18.9</td>
<td>0.7</td>
<td>22.2</td>
<td>0.9</td>
</tr>
<tr>
<td>Myalgia</td>
<td>26.9</td>
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<tr>
<td>Fever‡</td>
<td>0.6</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

*Study 2 (NCT03950856) was a randomized (1:1), double-blind, active comparator-controlled, lot to lot consistency study. Safety was monitored using a Vaccination Report Card (VRC) for up to 14 days postvaccination. The table represents the final assessment by the study investigators upon review of the VRC 15 days postvaccination, to ensure consistency with protocol definitions.

**Local Reactions***

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE Any</th>
<th>Grade 3†</th>
<th>Prevnar 13 Any</th>
<th>Grade 3†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>75.8</td>
<td>1.1</td>
<td>68.8</td>
<td>1.6</td>
</tr>
<tr>
<td>Headache</td>
<td>15.1</td>
<td>0.5</td>
<td>14.0</td>
<td>0.3</td>
</tr>
<tr>
<td>Myalgia</td>
<td>26.5</td>
<td>0.8</td>
<td>24.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>28.8</td>
<td>0.3</td>
<td>26.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Fever‡</td>
<td>12.7</td>
<td>0.4</td>
<td>11.6</td>
<td>0.0</td>
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**Systemic Reactions‡**

<table>
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<tr>
<th>Reaction</th>
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<th>Prevnar 13 Any</th>
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<td>68.8</td>
<td>1.6</td>
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<tr>
<td>Headache</td>
<td>15.1</td>
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<td>14.0</td>
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<td>0.3</td>
<td>26.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Fever‡</td>
<td>12.7</td>
<td>0.4</td>
<td>11.6</td>
<td>0.0</td>
</tr>
</tbody>
</table>

*Study 4 (NCT03547167) was a randomized (1:1), double-blind, active comparator-controlled, lot to lot consistency study. Safety was monitored using a Vaccination Report Card (VRC) for up to 14 days postvaccination. The table represents the final assessment by the study investigators upon review of the VRC 15 days postvaccination, to ensure consistency with protocol definitions.

**Local Reactions***

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE Any</th>
<th>Grade 3†</th>
<th>Prevnar 13 Any</th>
<th>Grade 3†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>34.3</td>
<td>1.0</td>
<td>36.8</td>
<td>0.8</td>
</tr>
<tr>
<td>Headache</td>
<td>26.5</td>
<td>0.8</td>
<td>24.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Myalgia</td>
<td>28.8</td>
<td>0.3</td>
<td>26.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>12.7</td>
<td>0.4</td>
<td>11.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Fever‡</td>
<td>1.0</td>
<td>0.3</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

**Systemic Reactions‡**

<table>
<thead>
<tr>
<th>Reaction</th>
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<th>Grade 3†</th>
<th>Prevnar 13 Any</th>
<th>Grade 3†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>34.3</td>
<td>1.0</td>
<td>36.8</td>
<td>0.8</td>
</tr>
<tr>
<td>Headache</td>
<td>26.5</td>
<td>0.8</td>
<td>24.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Myalgia</td>
<td>28.8</td>
<td>0.3</td>
<td>26.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>12.7</td>
<td>0.4</td>
<td>11.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Fever‡</td>
<td>1.0</td>
<td>0.3</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>
Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein). In studies conducted in the Americas, Europe and Asia Pacific, in which 5,630 adults 18 years of age and older were: injection-site pain (66.8%), myalgia (26.9%), fatigue (21.5%). The most commonly reported solicited adverse reactions in individuals 50 years of age were: injection-site pain (75.8%), fatigue (34.3%), myalgia (28.8%). The most commonly reported solicited adverse reactions in individuals 18 through 49 years of age were: injection-site pain (91.5%), fatigue (46.3%), myalgia (31.3%). The safety of VAXNEUVANCE was assessed in 7 randomized, double-blind clinical safety assessment in clinical studies.

**ADVERSE REACTIONS**

**CONTRAINDICATIONS**

Hold the prefilled syringe horizontally and shake vigorously. Administer a single 0.5 mL dose. Reactions in pneumococcal vaccine-naïve adults 50 years of age and older previously vaccinated with PNEUMOVAX 23 (at least 1 year prior to vaccine administration). The clinical studies included adults with stable underlying medical conditions (e.g., vaccination with PNEUMOVAX 23). In Study 7 (NCT03480802), HIV-infected adults without risk factors for pneumococcal disease (Study 4)*.

### Table 1: Percentage of Participants with Solicited Local and Systemic Adverse Reactions in Pneumococcal Vaccine-Naïve Adults 50 Years of Age and Older with Previous Pneumococcal Vaccination (Study 5)*

<table>
<thead>
<tr>
<th>Reaction</th>
<th>VAXNEUVANCE (%)</th>
<th>Prevnar 13 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>55.1</td>
<td>44.4</td>
</tr>
<tr>
<td>Any</td>
<td>0.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Grade 3†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erythema</td>
<td>7.9</td>
<td>7.1</td>
</tr>
<tr>
<td>Any</td>
<td>0.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Grade 3†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swelling</td>
<td>14.2</td>
<td>6.3</td>
</tr>
<tr>
<td>Any</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Grade 3†</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Systemic Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>18.1</td>
<td>19.0</td>
</tr>
<tr>
<td>Any</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Grade 3†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>13.4</td>
<td>15.9</td>
</tr>
<tr>
<td>Any</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Grade 3†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>15.7</td>
<td>11.1</td>
</tr>
<tr>
<td>Any</td>
<td>0.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Grade 3†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td>5.5</td>
<td>8.7</td>
</tr>
<tr>
<td>Any</td>
<td>0.0</td>
<td>0.0</td>
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<tr>
<td>Grade 3†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever‡</td>
<td>1.6</td>
<td>0.0</td>
</tr>
<tr>
<td>≥38.0°C and &lt;39.0°C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>≥39.0°C</td>
<td>0.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

*Study 5 (NCT02573181) was a randomized, double-blind, descriptive study. Safety was monitored using a Vaccination Report Card (VRC) for up to 14 days postvaccination. The table represents the final assessment by the study investigators upon review of the VRC 15 days postvaccination, to ensure consistency with protocol definitions.

†Solicited on Day 1 through Day 7 postvaccination.

‡Any use of narcotic pain reliever or prevents daily activity.

§Solicited on Day 1 through Day 14 postvaccination.

N=Number of participants vaccinated

Unsolicited Adverse Reactions

Across all studies, injection-site pruritus was reported to occur in up to 2.8% of adults vaccinated with VAXNEUVANCE.

Serious Adverse Events

Across all studies, among participants 18 years of age and older who received VAXNEUVANCE (excluding those who received QIV concomitantly; N=5,030) or Prevnar 13 (N=1,808), serious adverse events within 30 days postvaccination were reported by 0.4% of VAXNEUVANCE recipients and by 0.7% of Prevnar 13 recipients. In a subset of these studies, among those who received VAXNEUVANCE (N=4,751) and Prevnar 13 (N=1,532), serious adverse events within 6 months postvaccination were reported by 2.5% of VAXNEUVANCE recipients and by 2.4% of Prevnar 13 recipients.

There were no notable patterns or numerical imbalances between vaccination groups for specific categories of serious adverse events that would suggest a causal relationship to VAXNEUVANCE.

Safety with Concomitant Influenza Vaccine Administration

The safety profile was similar when VAXNEUVANCE was administered with or without inactivated quadrivalent influenza vaccine.

**DRUG INTERACTIONS**

Immunosuppressive Therapies

Immunosuppressive therapies may reduce the immune response to this vaccine.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

**Risk Summary**

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15 to 20%, respectively.

There are no adequate and well-controlled studies of VAXNEUVANCE in pregnant women. Available data on VAXNEUVANCE administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

Developmental toxicity studies have been performed in female rats administered a human dose of VAXNEUVANCE on four occasions; twice prior to mating, once during gestation and once during lactation. These studies revealed no evidence of harm to the fetus due to VAXNEUVANCE.

**Data**

Animal Data

Developmental toxicity studies have been performed in female rats. In these studies, female rats received a human dose of VAXNEUVANCE by intramuscular injection on day 28 and day 7 prior to mating, and on gestation day 6 and on lactation day 7. No vaccine related fetal malformations or variations were observed. No adverse effect on pup weight up to post-natal day 21 was noted.

Lactation

**Risk Summary**

Human data are not available to assess the impact of VAXNEUVANCE on milk production, its presence in breast milk, or its effects on the breastfed child. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for VAXNEUVANCE and any potential adverse effects on the breastfed child from VAXNEUVANCE or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine.

**Pediatric Use**

The safety and effectiveness of VAXNEUVANCE in individuals younger than 18 years of age have not been established.

**Geriatric Use**

Of the 4,389 individuals aged 50 years and older who received VAXNEUVANCE, 2,478 (56.5%) were 65 years and older, and 479 (10.9%) were 75 years and older. Overall, there were no clinically meaningful differences in the safety profile or immune responses observed in older individuals (65 to 74 years and 75 years of age and older) when compared to younger individuals.

**Individuals at Increased Risk for Pneumococcal Disease**

**Adults with HIV Infection**

In a double-blind, descriptive study (Study 7), the safety and immunogenicity of VAXNEUVANCE were evaluated in pneumococcal vaccine-naïve HIV-infected adults 18 years of age and older, with CD4 T-cell count ≥50 cells per microliter and plasma HIV RNA value <50,000 copies/mL. Participants were randomized to receive VAXNEUVANCE (N=152) or Prevnar 13 (N=150), followed by PNEUMOVAX 23 two months later. Anti-pneumococcal opsonophagocytic activity (OPA) geometric mean antibody titers (GMTs) were higher after administration of VAXNEUVANCE, compared to pre-vaccination, for the 15 serotypes contained in VAXNEUVANCE. After sequential administration with PNEUMOVAX 23, OPA GMTs observed at 30 days after PNEUMOVAX 23 vaccination were numerically similar between the two vaccination groups for all 15 serotypes contained in VAXNEUVANCE. The safety profile of VAXNEUVANCE was similar between the two vaccination groups. The effectiveness of VAXNEUVANCE in HIV-infected individuals has not been evaluated.

**NONCLINICAL TOXICOLOGY**

Carcinogenesis, Mutagenesis, Impairment of Fertility

VAXNEUVANCE has not been evaluated for carcinogenic or mutagenic potential or for impairment of male fertility in animals. VAXNEUVANCE administered to female rats had no effect on fertility.

**PATIENT COUNSELING INFORMATION**

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Discuss the following with the patient:

- Provide the required vaccine information to the patient.
- Inform the patient of the benefits and risks associated with vaccination.
- Inform the patient that vaccination with VAXNEUVANCE may not protect all vaccine recipients.
- Instruct the patient to report any serious adverse reactions to their healthcare provider who in turn should report such events to the vaccine manufacturer or the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967, or report online at www.vaers.hhs.gov.

For more detailed information, please read the Prescribing Information.

uspi-v114-i-2107-000

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[DRTP0422_CV2-003_Merck Vaxneuvance.indd] 5

3/25/22 9:57 AM
PUBLISHER’S NOTE

News just for you, 24/7

You might notice a new, small logo on the cover of this month’s issue, representing our Medical World News® channel. If you are not familiar with this 24/7 platform, I invite you to visit it as soon as you have the chance at www.medicalworldnews.com.

Now in its fifth season, this easy to navigate website dedicated to health care news offers viewers 6 shows:

- **Inside the Practice** highlights a unique, nonclinical aspect of a specialty— for example, a hospital’s celebration to mark a patient’s discharge.
- **Deep Dive** offers an in-depth exploration of a high-impact topic, such as COVID-19 vaccines and children.
- **Wellbeing Checkup** shares health care providers’ tips for staying mentally and physically healthy, including suggestions regarding regular exercise, proper nutrition, and meditation practice.
- **After Hours** reveals what clinicians do when they’re not working: They’re scuba diving, playing piano, traveling, and more.
- **Second Opinion** gives 2 medical experts a platform to discuss a compelling and timely health topic.
- **Behind the Science** poses the same question to multiple physicians, garnering a variety of perspectives on some of the most important issues in the health care space.

We hope you will take some time out of your hectic schedule to enjoy these programs! And, check out page 8 of this issue for a recap of a recent Drug Topics’ segment on stress management for pharmacist health. As always, thank you for reading.

Mike Hennessy Jr
President and CEO
EDITORIAL ADVISORY BOARD

LAKESHA M. BUTLER
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COVER STORY

KEYS TO MITIGATING

MEDICATION USE DISPARITIES

PAGE 16

PAGE 10

PAGE 11

PAGE 15

PAGE 28

PAGE 22

PAGE 23

PAGE 18

PAGE 20

PAGE 24

PAGE 27

PAGE 25

PAGE 19

PAGE 17

PAGE 14

PAGE 13

PAGE 12

PAGE 35

PAGE 34

PAGE 33

PAGE 32

PAGE 31

PAGE 30

PAGE 29

PAGE 26

PAGE 21

PAGE 26

PAGE 27

PAGE 28

PAGE 29

PAGE 30

PAGE 31

PAGE 32

PAGE 33

PAGE 34

PAGE 35

PAGE 36

PAGE 37

PAGE 38

PAGE 39

PAGE 40

PAGE 41

PAGE 42

PAGE 43

PAGE 44

PAGE 45

PAGE 46

PAGE 47

PAGE 48

PAGE 49

PAGE 50

PAGE 51

PAGE 52

PAGE 53

PAGE 54

PAGE 55

PAGE 56

PAGE 57

PAGE 58

PAGE 59

PAGE 60

PAGE 61

PAGE 62

PAGE 63

PAGE 64

PAGE 65

PAGE 66

PAGE 67

PAGE 68

PAGE 69

PAGE 70

PAGE 71

PAGE 72

PAGE 73

PAGE 74

PAGE 75

PAGE 76

PAGE 77

PAGE 78

PAGE 79

PAGE 80

PAGE 81

PAGE 82

PAGE 83

PAGE 84

PAGE 85

PAGE 86

PAGE 87

PAGE 88

PAGE 89

PAGE 90

PAGE 91

PAGE 92

PAGE 93

PAGE 94

PAGE 95

PAGE 96

PAGE 97

PAGE 98

PAGE 99

PAGE 100

PAGE 101

PAGE 102

PAGE 103

PAGE 104

PAGE 105

PAGE 106

PAGE 107

PAGE 108

PAGE 109

PAGE 110

PAGE 111

PAGE 112

PAGE 113

PAGE 114

PAGE 115

PAGE 116

PAGE 117

PAGE 118

PAGE 119

PAGE 120

PAGE 121

PAGE 122

PAGE 123

PAGE 124

PAGE 125

PAGE 126

PAGE 127

PAGE 128

PAGE 129

PAGE 130

PAGE 131

PAGE 132

PAGE 133

PAGE 134

PAGE 135

PAGE 136

PAGE 137

PAGE 138

PAGE 139

PAGE 140

PAGE 141

PAGE 142

PAGE 143

PAGE 144

PAGE 145

PAGE 146

PAGE 147

PAGE 148

PAGE 149

PAGE 150

PAGE 151

PAGE 152

PAGE 153

PAGE 154

PAGE 155

PAGE 156

PAGE 157

PAGE 158

PAGE 159

PAGE 160

PAGE 161

PAGE 162

PAGE 163

PAGE 164

PAGE 165

PAGE 166
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Manage Your Stress for Your Best Health

A personal medical diagnosis led one pharmacist on a journey of health and healing.

By Lauren Biscaldi

Jennifer Bourgeois, PharmD, is something of an expert on stress. After receiving a diagnosis of chronic Epstein-Barr virus, Bourgeois realized that the headaches and fatigue she had been experiencing were more than just the symptoms of being a working mom.

In a recent episode of Well-being Checkup, Bourgeois sat down with Drug Topics® to chat about the ways in which stress can wreak havoc on both body and mind, and the company she founded—Well & Free, LLC—to help others manage stress in their lives.

Drug Topics®: What inspired you to start your business? Can you share a bit about the journey that you took to get there?

Jennifer Bourgeois, PharmD: [A] personal medical diagnosis got my attention that maybe I wasn't doing such a great job with my own health. A few years back, I was diagnosed with chronic Epstein-Barr virus. The extreme fatigue that I tried to write off as normal—because I was a working mom—wasn't so normal, and it was accompanied with headaches and fatigue, among other symptoms. Once I received the diagnosis, that's really when I started to get serious and committed to my own well-being. That took me into this new field of functional and integrative medicine, and that's where I found true healing and was able to identify the root cause of my chronic conditions, which was stress.

I think stress is something that we could talk about all day, especially in the pharmacy and medical communities. Stress is something that's very real; it's very palpable for all of us in day-to-day life.

Drug Topics®: Especially in today's environment, many health care providers can likely relate to the idea of being overscheduled and unable to rest, which I think really can affect chronic stress. So, how can that overpacked schedule negatively impact well-being?

Bourgeois: That's such a great question. So, what we find is that when we are overscheduled, for most of us, our body perceives that as stress. We all have different triggers of stress; that's why we say stress can be subjective—it's the triggers...that's the subjective part. What causes your body to perceive stress could be different than mine.

But when your body does perceive that stress, there is a physiological response that happens. Oftentimes, when we're overscheduled, we feel stressed because the demands of what's happening in our life exceed the resources. We've gotten ourselves into a position [where] we have way too many things to do and not enough time, and our body perceives that as stress. This stress starts this physiological process that happens that literally changes the way our body responds and affects the way that we can rest. Our nervous system [turns on our] fight-or-flight mode where we're very stimulated. What we need to do to allow our body to rest is, we must shift our nervous system back into the parasympathetic state. That's where we're going to find rest and rejuvenation, and all those things that are so important for us, because...if our body doesn't get the rest it needs, it will negatively impact our overall health.
Sarahren Martin is a 45-year-old White woman who, 6 months after being hospitalized and receiving a type 2 diabetes diagnosis, goes to her community pharmacy to attend a diabetes education class. Before the class, she asks the pharmacist to check her blood sugar, which typically ranges from 250 mg/dL to 280 mg/dL and averages 200 mg/dL while fasting.

When speaker Tamara A. McCants, PharmD, an assistant professor at Howard University in Washington, DC, asked the audience at an American Pharmacists Association 2022 Annual Meeting and Exposition session what opportunities for collaboration between community and health system pharmacy might look like when caring for Martin, suggestions began to fly. One attendee suggested point-of-care testing as an opportunity for collaboration, with community pharmacy taking the lead. But as another attendee pointed out, health system pharmacies have access to labs.

A third attendee asked who would be getting paid for these services, whereas a fourth suggested that Martin—who takes 1000 mg metformin twice daily and has gained 10 lb in the past year—should have received a referral to a diabetes education class on hospital discharge.

“There’s no right or wrong answer,” said McCants, “but one thing I want us to highlight in this discussion is, there was a lot of finger-pointing as to who should have done what, and why they didn’t, and ‘we need to do this,’ and ‘we’re better at that.’ And that is not the environment for collaboration.” Opportunities for collaboration between community and health system pharmacists are widespread, said McCants, acknowledging that each practice type has access to different tools to help patients. Health system pharmacists can, for example, review and address labs. “No matter how much we want to do that in a community pharmacy, we just don’t have access to that—not yet,” she said.

When providing transitional care services—including medication counseling, bedside delivery, medication access, and treatment monitoring—patients benefit from cross-practice collaboration. Pharmacists are perhaps the health care provider most aware of a patient’s health insurance plan and accessible medications.

Comprehensive medication management is another opportunity for collaboration; both community and health system pharmacists can develop a care plan to achieve optimal outcomes, ensure that the patient agrees with and understands the care plan, document steps and clinical status, and conduct follow-up evaluations. Disease states like diabetes, psychiatric conditions, and HIV can all be targeted for collaborative efforts—due partially to requirements to manage these diseases, but also because these conditions are financially beneficial to community and health system settings.

“In order for us to have successful collaboration, there has to be a real conversation about who is going to pay,” said McCants, “and what the payment mechanisms are.”

When it comes to the fictional Sarah Martin, “the No. 1 incentive here...is her insurance company does not want her to end up back in the hospital,” McCants pointed out. To collaborate successfully, start there.

“Before I did this presentation, I would have been just like you, trained in community pharmacy and knowing what community pharmacy can do. But we’re still not the best equipped because we don’t have access to all of the information,” McCants said. “And so, we have to understand, and be OK with, who has access to information, and who it makes the most financial sense for.”

“As a profession...we have to talk to each other about all of the biases we have,” she added. “We have to lay that all aside if real collaboration—successful collaboration—is going to occur. The only way to do that is to put the patient in the forefront.”

For references, visit drugtopics.com.
For the first time since 2019, American Pharmacists Association Annual Meeting and Exposition attendees gathered in person for the annual OTC update, this year covering products that have come to market—or been recalled—since 2020.

Daniel Krinsky, MS, RPh, owner and president of EduCare4U and PGx101, dove into the presentation, beginning with a long list of product recalls that have affected the OTC market since 2020. Many, he said, were due to contamination, including the presence of lead in a watermelon-flavored cannabidiol (CBD) oil tincture and 2 brands of sunscreens containing benzene. A list of tainted sexual enhancement products covered 4 slides—a “common thread” in every OTC Update presentation, said Krinsky.

New OTC products and products that underwent a prescription-to-OTC switch included diclofenac sodium 1% topical gel (Voltaren), AleveX, and Vazalore 81-mg and 325-mg liquid-filled caps. Alcaftadine ophthalmic solution 0.25% (Lastacaft), an ocular antihistamine, is also available online and in other retailers.

“I mention this every year, [but] I think some of these products are best kept near the pharmacy [counter] to allow us to take advantage of opportunities with our patients,” said Krinsky, adding that there may be challenges from a merchandising perspective in separating products that are in similar categories.

Several new immune support products have flooded the market, not all of which come from mainstream companies. CBD products have also made their way onto shelves, a result of interest in both CBD and medical marijuana. But regulation of CBD products is lacking, with dosing and dosage form “all over the place,” said Krinsky. “It’s a very complex situation [and] it’s confusing as a pharmacist to help [individuals] understand what makes sense and what might be worth talking about vs what is probably worth ignoring.”

Krinsky also pointed out that oral contraceptives have started to cement themselves firmly in the pharmacists’ wheelhouse, although pharmacist dispensing without a prescription is regulated on a state-by-state basis. In another notable change, sale of cough suppressant dextromethorphan is now restricted to adults 18 years or older in 21 states, requiring an ID check like that required to purchase products containing pseudoephedrine.

Later, Stefanie Ferreri, PharmD, Henry L. Smith & James L. Olsen Distinguished Professor at the UNC Eshelman School of Pharmacy in Chapel Hill, North Carolina, presented a case study: JW, age 37 years, seeking a recommendation for OTC treatment of her runny nose, clear nasal discharge, itchy eyes, and sore throat.

“There are a lot of differential diagnoses happening in my head right now,” Ferreri said. Pollen season, she said, has grown by 20 days, with 21% more pollen, over the last 40 years. Climate change is creating pollen seasons that are longer and more severe—and associated with subsequent worse outcomes for patients living with asthma and allergies.

For JW, either monotherapy with an intranasal corticosteroid or second-generation oral antihistamine might be appropriate, said Ferreri, encouraging attendees to remember the exclusion criteria for allergic rhinitis: children younger than 12 years, women who are pregnant or lactating, and those exhibiting symptoms of nonallergic rhinitis, otitis media, sinusitis, bronchitis, or lower respiratory diseases. For ocular symptoms, OTC options might include artificial tears, topical olopatadine, or topical ketotifen.

When using OTC products to treat allergic rhinitis, pharmacists have an opportunity to engage in follow-up, an area where, Ferreri said, “we as a profession—where most of health care—falls short.” Monitoring and follow-up is the last part of the pharmacist-patient care process, and pharmacists “can really do a great job in this area.”

For references, visit drugtopics.com.
When a patient presents with oral pain, Jill Morgan’s advice is simple: Ask questions. That’s because a patient may experience oral pain for various reasons from a canker sore to tooth pain, a wire sticking out of braces, or a burn on the roof of the mouth after eating a hot slice of pizza.

“It’s always the pharmacist’s responsibility to help our patients sort through when an OTC medication is appropriate and when they need to be seen by a health care provider,” said Morgan, PharmD, BCPS, associate professor and chair in the Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy in Baltimore. “There are so many [OTC] products that it’s overwhelming. No matter how much burnout there is or how overwhelmed we are with work, at the end of the day, patients are our main priority.”

If a patient arrives at the counter with a canker sore, an OTC treatment such as benzocaine may be appropriate because it will help protect the ulcer while the patient is eating, she explained. According to the Cleveland Clinic, canker sores—which can be painful—are found inside the mouth; they can be caused by stress, a minor injury, or consuming acidic fruits and vegetables or hot, spicy foods.

With benzocaine, Morgan advised, it is important to tell patients that using too much can cause methemoglobinemia, a condition in which the amount of oxygen carried through the blood is greatly reduced. Patients should not swallow benzocaine because it can increase the likelihood of seizures; this is a greater concern for children and for adults who already have a seizure condition, she added. Because of the risk of methemoglobinemia, the FDA advises against the use of OTC oral drug products for teething infants and children 2 years or younger.

With tooth pain—especially pain associated with having wisdom teeth removed—Morgan explained that Motrin (ibuprofen) should help; still, the pain should not last long and can also be treated using a wet tea bag.

Patients wearing braces can experience pain due to wires poking the inside of their cheek, said Morgan. Wax products can help, along with mouth rinses, both of which are typically provided by orthodontists. Although Motrin is also an option, patients should see their orthodontist if the pain persists because ongoing irritation from the wires could cause infection, Morgan said. It’s also important to ask patients whether they have a fever or if the cheek area is warm to the touch, recommended Morgan, noting that both symptoms are signs of an infection.

Treating burns inside the mouth can be a challenge. If a patient burns the roof of their mouth while eating pizza, there is not much a pharmacist can do to help. Morgan’s advice for patients experiencing minor pain is to recommend that they drink cool liquids or do a saltwater rinse. If the pain is particularly intense, the patient should see a physician, she said.

For references, visit drugtopics.com.

How do you help treat oral pain in your pharmacy? Email your comments to lbiscaldi@mjhlifesciences.com.
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Across KLOXXADO’s™ two PK studies, adverse reactions were reported in two subjects for each of the following: abdominal pain, asthenia, dizziness, headache, nasal discomfort, and presyncope.

Risk of Recurrent Respiratory & CNS Depression; Risk of limited efficacy with partial agonists or mixed agonist/antagonists; Precipitation of severe opioid withdrawal; Risk of CV effects

See full ISI on back.
CONTRAINDICATIONS
• Hypersensitivity to naloxone hydrochloride or to any of the other ingredients in KLOXXADO™

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Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses of naloxone hydrochloride may be required.

• Precipitation of Severe Opioid Withdrawal
Use in patients who are opioid-dependent may precipitate opioid withdrawal characterized by body aches, diarrhea, tachycardia, fever, runny nose, sneezing, pилоерекция, sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may include convulsion, excessive crying and hyperactive reflexes. Monitor the patient for the development of the signs and symptoms of opioid withdrawal. For more information about management of opioid withdrawal, see the full Prescribing Information.

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References


4 NARCAN® (Naloxone HCl) Nasal Spray [prescribing information]. Plymouth Meeting, PA: Adapt Pharma, Inc.; 2020

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AROUND THE PRACTICE

Opioid Abuse and the Role of Naloxone

Are you prepared to address the opioid epidemic?

That was the overarching theme of the latest Drug Topics® Around the Practice series, titled “Opioid Abuse and the Role of Naloxone.” Moderator Matthew A. Torrington, MD, a family medicine physician in Culver City, California, was joined by panelists DanielBuffington, PharmD, president and CEO of Clinical Pharmacology Services in Tampa, Florida; Bill H. McCarberg, MD, founder of the Chronic Pain Management Program for Kaiser Permanente and an adjunct clinical professor at the University of California, San Diego School of Medicine; and Thomas R. Kosten, MD, the JH Waggoner Endowed Chair and professor of psychiatry, pharmacology, immunology, and neuroscience, vice chair for psychiatry, and codirector of the Dan L. Duncan Institute for Clinical and Translational Research at the Baylor College of Medicine in Houston, Texas; for a wide-ranging 6-part discussion on the current state of the opioid epidemic and how naloxone can help.

The Opioid Epidemic and Fentanyl

“One of the most striking things is that this isn’t a new epidemic,” said Kosten. “This is one that has had its onset around 2015—certainly by 2017. One can say it was led into by the overprescribing of opioids, but what has taken over is fentanyl.”

Manufactured in China and Mexico, fentanyl is imported into the United States. According to Kosten, the country is currently in the grips of the fourth wave of that epidemic, one in which fentanyl is being disguised. “It’s being mixed in with heroin and methamphetamine and cocaine, because it’s all white powder.” Online, it’s being marketed as pills that look like Percocet, Adderall, and Valium. But each of these products contains a variable amount of fentanyl—with enough in some pills for just 1 or 2 to kill you.

According to Kosten, the latest data suggest that the average age of those who overdose on opioid medications is 75 years of age. “We’re talking about older Medicare and Medicaid recipients,” he said. “This is a group of people who are buying medications on the internet because of prices, and what they’re getting is fentanyl. They’re dying from it.”

“It’s a whole different paradigm,” McCarberg added. “It’s because they can’t afford [their medications] in the regular pharmacy, because it’s all white powder.” Online, it’s being marketed as pills that look like Percocet, Adderall, and Valium. But each of these products contains a variable amount of fentanyl—with enough in some pills for just 1 or 2 to kill you.

Approaches to Pain Management

The opioid epidemic has touched every part of the United States. But how, asked Torrington, has it changed the way in which clinicians manage pain? “It’s incredibly ironic that as physicians have clamped down on furnishing patients with opioids for pain...overdose deaths have gone up and continue to go up.”

McCarberg noted that his primary care colleagues are frequently hesitant to prescribe opioids, regardless of the patient’s pain condition—including in hospice and palliative care settings. “I’ve noticed more reluctance,” he said, “and these are people that are dying. They have a cancer diagnosis; they’re dying, but they’re cared for by caregivers who are the risk population. They’re the ones who are stealing Grandma’s oxycodone and using it illegally.”

Kosten shared his involvement in several cases where primary care physicians had been prosecuted by local police and the United States Drug Enforcement Administration due to the illicit prescribing of opioids, known as pill mills. But, he said, “these are primary care doctors. Less than 10% of their practice involves prescribing pain medications [and] they’re prescribing...at quite modest doses.” It’s an extreme reaction, he explained. “[It’s] spread to prosecuting doctors who’ve been willing to take on difficult pain management cases that were abandoned.”

Challenges With Opioid Use

Buffington suggests that when pain management patients transition to primary care, health care providers should begin by assessing individual pain needs along with therapeutic options. “Scrutiny may arise from a law enforcement agency that’s not well versed or skilled in health care matters,” he said. “We’re seeing that in the pharmacy as well.”

He went on to describe an “odd expectation” for a continuity of records providing a duplication of work product. “The Controlled Substances Act states that there’s a corresponding responsibility between the prescriber and the pharmacist to assess that, and there are some very unrealistic expectations in law enforcement that those parties are completely aware of what each is doing.” Buffington pointed this out not to diminish the need for communication and patient safety, but rather to highlight the access issues that it leads to.

“It’s causing a pharmacy that doesn’t know a patient well to refuse a prescription out of concerns,” he said.

“The other point,” McCarberg added, “is that pharmacies and pharmacists are being held accountable for the crisis, namely that the pharmacist should have known that this was an illegal prescription and that it wasn’t for a pain problem. How would a pharmacist know? They don’t have a record.”

Buffington explained that what pharmacists are finding is that
“law enforcement, whether it’s DEA-driven or not—has come up with what it considers enforcement metrics for an investigation that aren’t published or applicable or standard in any other setting...and expect that somehow, physicians or pharmacists are supposed to be all-knowing.” He added, “This external pressure from law enforcement and government agencies...is hurting or hindering the process, rather than ensuring better safety.”

Prescription drug monitoring plans used to allow a health care provider to view patient listings and see that a patient was, for example, getting opiates from 6 different doctors. “You rarely see that anymore,” said Kosten.

Using Naloxone Against Opioid Use

“My story with naloxone starts in the mid-2000s,” said Torrington, “I was like, ‘Everybody needs to have naloxone around...’...When somebody had an overdose, nobody wanted to call 911. When they did, they were terrified.”

Torrington turned to the panelists to share their experiences with naloxone, experience that vary across the country.

“In my state, most of the overdoses have fentanyl in them,” said Kosten. “This means 1 dose of your standard naloxone 0.4 mg given intramuscularly or even 2 mg given intranasally is simply not going to be enough to override that overdose.” Patients frequently require 2, 3, or 4 doses of naloxone to bring them back, and in some times “half their police department budget is buying naloxone.” Some newer products, he added, like 8 mg intranasal naloxone, are likely to become the standard due to the cost effectiveness when used with a fentanyl overdose.

Multiple studies in the last few years have tracked the average number of standard naloxone administrations in the face of higher-dose fentanyl products, said Buffington. “The percentage of time you’re having to do multiple [injections]—...in some studies they’re taking 5 administrations to reverse the effect—is absolutely a driver and a patient safety need.”

Three organizations—the FDA, the American Medical Association, and the CDC—have all requested that higher dose naloxone be made available. These new products were approved in April and October 2021, but the FDA approval process was not, McCarberg noted, stringent. “They didn’t have double-blind placebo-controlled trials, but they recognized that we need to get more [naloxone].”

Distributing naloxone simultaneously with products that carry a risk of overdose, like opioids or benzodiazepines, is a good thing, Buffington pointed out. It’s both a secondary deterrent and a benefit to the patient. In California, it’s a requirement to distribute naloxone to these patients, Torrington added. “You’re teaching them that the need to call for EMS, stay with the person, keep reassessing a risk of overdose, like opioids or benzodiazepines, is a good thing, Buffington pointed out. It’s both a secondary deterrent and a benefit to the patient. In California, it’s a requirement to distribute naloxone to these patients, Torrington added. “You’re teaching them that the need to call for EMS, stay with the person, keep reassessing...”

And, he said, it’s important to remember that just because naloxone is administered doesn’t mean that there’s no need to call 911. “My analogy is that it’s like a fire extinguisher or an automated external defibrillator (AED). If you’ve ever had to use [an AED] in public, it’s not like you’re not going to call 911—someone just had a cardiac event. They’re not done...it’s just the first step.”

Dealing With a Fentanyl Overdose

“We always think of fentanyl as a short-acting drug—quick on, quick off,” said Kosten. “But in fact, it’s not quick off for anyone who’s a chronic user because it’s very lipid soluble, so it goes into all the lipids and fatty tissues...and slowly comes out.” Slowly, in this case, means that the half-life of fentanyl varies based on how long a person may have been chronically using.

Naloxone, on the other hand, is short-acting. So just 1 dose of naloxone for a fentanyl overdose may not last long enough.

“This is a critical lesson that we’re learning,” he added. “When the EMS gets there...the person is back in overdose.”

Educating Family on Naloxone and Overdoses

Educating families on naloxone—and on what an overdose can look like—is crucial, said McCarberg. It’s important to explain to families what an overdose might look like: “They’ll be overly sleepy, difficult to wake up, [they’ll] act like they’re drunk and won’t be themselves.”

McCatherine encourages families of patients to remember these symptoms, which he reinforces through handouts.

Buffington added that those in overdose can experience changes in skin color, as well as discernable slowing of their breathing rate or abnormal snoring. “After that first dose [of naloxone]...don’t let them go back to bed or fall asleep. If you feel the need to call for EMS, stay with the person, keep reassessing them, and debate the second or third dose if available.”

And, Kosten pointed out, it’s important to keep in mind that naloxone doesn’t reverse overdoses related to sedatives or alcohol use. For benzodiazepines, flumazenil is an option, but there’s some reluctance to use it. “If you give too much of it, you precipitate a seizure...so you can be in even bigger trouble,” he explained. “It’s very short acting, so you’re going to have to repeatedly [administer it] because benzodiazepines are very long acting.”

Moderator Matthew A. Torrington, MD, shared the case of a 27-year-old man who presented with extreme pain in his right ankle, ribs, and arm after a car crash. His past medical history is significant for substance use disorder and he takes buprenorphine 2 mg per day. After receiving a cast for his right ankle, he was started on oxycodone hydrochloride/acetaminophen 5/325 g. Is this patient a candidate for naloxone? Scan the QR code to watch the discussion and learn more.
IMPROVING HEALTH CARE AND MEDICATION ACCESS FOR MINORITY POPULATIONS

Across the country, minority populations face significant disparities in medication use.

It’s time for that to change.  By Frieda Wiley, PharmD
he tentacles of racial and cultural health care disparities extend their reach deep into the fabric of American culture. The complexities are painfully entrenched throughout American identity: from where a person lives and their cultural identity to one’s complexion and economic standing. Sadly, a patient’s experience accessing and navigating the United States health care system also falls on this list, an unfortunate consequence of inherent bias borne from all too common effects of systemic racism and implicit biases. Although many factors contribute to the substandard experiences marginalized communities face in the health care setting, perhaps no reason bears greater weight than the basis on which our health care system was founded.

From health care access to medication use disparities, minority populations often bear the brunt of a system not weighted in their favor. While the problem isn’t new—the CDC published a Health Disparities and Inequalities Report in a 2013 issue of *Morbidity and Mortality Weekly Report* (MMWR)—the COVID-19 pandemic threw many of the issues surrounding care equity into sharp relief.

“All patients—regardless of gender or race—want to be provided with care that treats and engages them with respect. Understanding the concept of cultural humility will go a long way for people to learn who to improve the health literacy for patients from different backgrounds so that they will be more responsive to medication therapies.” —Donney John, PharmD, executive director of NOVA Scripts Central in Falls Church, Virginia
Three Tips to Tackle Health Care Disparities

Donney John, PharmD, executive director of NOVA ScriptsCentral in Falls Church, Virginia, shared these tips to help pharmacists manage medication use disparities in minority populations.

1. Be humble. “Practice cultural humility in order to develop your skills to provide culturally competent care.”

2. Practice what you preach. Take initiative to effect positive changes through educational and outreach initiatives. NOVA ScriptsCentral launched its Educate Before You Medicate health program to teach patients proactively about their medications. One core element of its program included researching cultural and societal stigmas associated with relevant health topics.

3. Educate Before You Medicate. Three Tips to Tackle Health Care Disparities

Research throughout the pandemic has shown that some racial and ethnic minority groups are more likely, disproportionately so, to be negatively impacted by COVID-19. The reason is multifaceted: in some communities, racial and ethnic minorities were more likely to be working essential service jobs, increasing the risk of exposure to SARS-CoV-2. And because of systemic disparities in care access, many of these individuals were already living with conditions predisposed to experience worse COVID-19 outcomes.

Even after treatments like monoclonal antibodies became available, a MMWR report found that of a total of nearly 6 million patients in PCORnet health care systems evaluated, “mean monthly (monoclonal antibody use) among all patients with positive SARS-CoV-2 test results” were lower among patients who were Black, Asian, Hispanic, or non-Hispanic compared with patients who were White. 3

Socioeconomic Factors Contribute to Disparities

Both race and socioeconomic standing play roles in dictating a person’s success. A person’s financial background can, for example, be an indicator of their overall health. In fact, personal wealth is so predictive of individual health outcomes and overall health that the scales remain drastically imbalanced and in favor of those with financial security.

“The United States health care system was designed by and set up to care for White people, so of course, it does the best job caring for White people,” said Andrew Schmelz, PharmD, assistant professor of pharmacy practice at Butler University in Indianapolis. “Because our health care system is structured around businesses and management of payment and profit, how much money someone has directly impacts how healthy they are,” Schmelz told Drug Topics®.

Language Differences Create Barriers

Language barriers can further amplify health care and medication use disparities. “One contributing factor to the low incidence of medication use [among] Latino and Asian communities is a lack of health literacy due to language barriers,” Donney John, PharmD, executive director of NOVA ScriptsCentral in Falls Church, Virginia, told Drug Topics®.

Across the spectrum, members of non–English-speaking communities...
may not feel comfortable asking questions of their health care provider, concerned about appearing as if they are “questioning” or not respecting their provider’s knowledge and training, John explained. And sometimes, medication information is not translated into a language that patients can easily understand, leading to vital information being lost in translation. John encourages pharmacists and other health care professionals to seek resources other than Google Translate. Although this tool can be beneficial in day-to-day life, multiple instances of inaccurate translation of medication-related information have been noted.10

Misunderstandings and patient engagement hesitancy owing to language barriers are not the only factors leading to disparity in the health care system. In some communities, individuals may prefer to turn to alternative healing practices, which could result in lower medication use. Once again, cultural idiosyncrasies make the situation more difficult to quantify.

“I would argue that non-Hispanic White [individuals] may also follow these practices and have some more common to their own culture—for example, doing “cleanses” to remove “toxins” from the GI tract,” Schmelz said. “Also, medication use for specific diseases (eg, drugs for opioid use disorder) has been historically stigmatized, and populations with higher incidence of these problems [are] disproportionately affected.”

**DE&I Initiatives, Accelerated**

The murder of George Floyd by police in 2020 ignited widespread discussions around diversity, equity, and inclusion (DE&I), said Schmelz. Although encouraging, DE&I as a field isn’t new and there is skepticism that this increased attention will result in any meaningful changes in how we train students or how we provide care.

Frank North, PharmD, MPA, president-elect of the National Pharmaceutical Association in Houston, shared similar concerns regarding how meaningful changes look and whether they are effective.

“DE&I is [a] hot topic we see schools implementing, but is it done so in an effective way?” he asked.

“Some institutions are wrapping their minds [around] the need for DE&I and the fact that communities of color have different experiences.”

These efforts are wide ranging, with some centered around research11 into the implicit biases—“attitudes or stereotypes that affect our understanding, actions, and decisions in an unconscious manner”—on pharmacy education.

**Cultural Competency: An Outdated Concept?**

Education can help create awareness among providers about their own implicit biases while providing strategies to provide more culturally competent care. However, this isn’t a panacea for health care disparities; cultural competence—the ability to understand, appreciate, and interact with individuals from cultures different from one’s own—requires grace and introspection.

“All patients, regardless of gender or race, want to be provided with care that treats and engages them with respect,” he said. “Understanding the concept of cultural humility will go a long way for people to learn who to improve the health literacy for patients from different backgrounds so that they will be more responsive to medication therapies.

The narrative of cultural competency, while important, has 2 major limitations.13 First, it inadvertently introduces bias and stereotyping by implying that a person can collect information about group of people; and second, it creates the false notion that cultural competence is an area in which a person can become 100% proficient. Evidence suggests that cultural competence is on its way to becoming an antiquated concept—perhaps rightfully so. Its origins date back to the ‘60s and ‘70s, an era marked by sociopolitical turbulence.

Cultural humility, a second-generation iteration of cultural competency, first emerged in 1998.13 The term acknowledges the fluidity of culture predomination while recognizing that understanding and honoring one’s culture is a lifelong process that commands reflection and introspection.

Empathy is another critical piece to solving the health care disparity puzzle, especially when it comes to engaging the patient with practical action points. “As a pharmacist, I don’t like to take medication myself, so I may not be as adherent to medication regimens if they are too cumbersome,” John admitted. “So, I try to put myself in the patient’s shoes and think [about whether] I could follow through on the recommendation that I am asking them to follow.”

How are you addressing health care disparities? Email your comments to lbiscaldi@mjhflifesciences.com.

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Vaccination errors are common but preventable mistakes. By Keith Loria

Vaccination errors have always occurred, but an increased demand for vaccines and workforce shortages have increased the possibility for errors at the pharmacy. Historically, the most common vaccination errors are the wrong vaccine, the wrong age for vaccination, and the wrong vaccine dose. Most errors occur due to lack of time, being rushed, impatience, lack of staffing, or everyone showing up at the same time or when the pharmacy is about to close.

“It is so easy to skip steps and think you have done this 1000 times, so what could go wrong? The best advice is to approach each vaccination with care,” said Simona Dorf, PharmD, BCMAS, clinical pharmacist manager for First Databank. “Check the vaccine administration record form carefully before mixing or drawing up the vaccine and scan the barcodes to ensure the same vaccine that is billed is being prepared for administration.”

Jay Phipps, PharmD, president and CEO of Phipps Pharmacy in Jackson, Tennessee, noted administration technique–related vaccination errors have increased recently. These include shoulder injuries related to vaccine administration, use of the wrong needle size, and the administration of a dose lower than authorized.

Limiting Mistakes
Numerous safeguards can be put in place to keep vaccination errors from happening, such as creating physical barriers for vaccine storage. Phipps noted the importance of developing a plan for vaccine storage in refrigerators and freezers that is well organized and properly labeled.

“It is so easy to skip steps and think you have done this 1000 times, so what could go wrong? The best advice is to approach each vaccination with care.”

SIMONA DORF, PHARMD, BCMAS, CLINICAL PHARMACIST MANAGER FOR FIRST DATABANK

“We should also be more aware of our environment,” Phipps added. “If it’s too crowded, the personnel can become distracted. Additionally, if someone is being administered to, they can’t be left unattended.”

One overlooked vaccine error can result from inappropriate vaccine storage. The CDC recommends storing vaccines in separate, self-contained units that only refrigerate or only freeze. If a combination refrigerator/freezer must be used, only refrigerated vaccines should be stored in the unit, and a separate standalone freezer should be used for frozen vaccines.

Another thing that can help eliminate errors is utilizing a separate area for vaccine preparation. “[Preparation and] administration should be in a separate area away from distractions and interruptions,” Phipps said. “Reference material should be posted that includes vaccines dilution requirements, if applicable; storage; route of administration; and length of needle for each vaccine at the pharmacy. A Do Not Disturb sign is also recommended when vaccines are being prepared or administered.”

“Immediately prior to administration, the patient’s name, date of birth, vaccine type, and number of shots in the series should be confirmed,” Phipps said. “Although the workload of all pharmacy staff is significant, the short amount of time to confirm the information is insignificant in comparison with the potential for error.”

Vaccine Delivery
If a pharmacist is making travel vaccine recommendations, they must carefully review the patient’s travel itinerary and pay particular attention to not only the country to which the
Avoiding Vaccination Errors

Vaccine administration errors are preventable. Follow this checklist to ensure your pharmacy is following vaccination best practices.

**ERROR: Wrong vaccine, administration site, or dosage**
- Circle important information on vaccine packaging to highlight differences between vaccines.
- Include brand names with vaccine abbreviations whenever possible.
- Separate vaccines into containers based on type and formulation.
- Store look-alike vaccines in different areas of the storage unit.
- When possible, purchase products with look-alike packaging from different manufacturers.
- Establish interruption-free areas or times when vaccines are being prepared or administered.
- Prepare vaccines for 1 patient at a time.
- Prepare the vaccines you will be administering. Do not administer vaccines prepared by someone else.

**ERROR: Scheduling errors**
- Use standing orders if and when appropriate.
- Create procedures to obtain a complete vaccination history via the immunization information system, patient medical records, and personal vaccination records.
- Implement vaccine administration training into orientation process.
- Post current immunization schedules for quick reference.
- Counsel patients on the importance of maintaining their immunization records.

**ERROR: Documentation errors**
- Avoid using error-prone abbreviations to document vaccine administration.
- Use the Advisory Committee on Immunization Practices’ vaccine abbreviations.

**ERROR: Administration of improperly stored and/or handled vaccines**
- Implement training for vaccine storage and handling requirements based on manufacturer guidelines or requirements.
- Rotate vaccines. Those with the earliest expiration dates should be at the front of the storage unit.
- Remove expired vaccines and diluents from storage units where viable vaccines are stored.
- Isolate vaccines exposed to improper storage temperatures.

**ERROR: Scheduling errors**
- Verify patient identity via name and date of birth prior to vaccine administration.
- Educate staff on eliminating unnecessary distractions and interruptions when administering vaccines.

Source: Adapted from the CDC

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Telepharmacy is on a roll. In 2001, when North Dakota became the first state to enact regulations allowing the practice, by early 2023, 28 states will allow some form of telepharmacy, and Kansas is poised to finalize regulations later this year, according to telepharmacy services provider TelePharm. Approval is advancing in other jurisdictions as well.

“Through the pandemic, there has been a drastic uptake in technology, especially remote technology,” said Brett H. Barker, PharmD, vice president of operations for NuCara Pharmacy, which operates physical stores and telepharmacies in Illinois, Iowa, Minnesota, North Dakota, and Texas. “I think we jumped forward a decade in about 2 weeks back in March 2021 with individuals’ comfort levels, uptake, and acceptance of remote care. Telepharmacy is good for patients, good for communities, and good for pharmacists.”

Telepharmacy is also a challenge. Roughly 40% of states do not allow telepharmacy, cautioned Mary Ann Kliethermes, PharmD, director of medication safety and quality for the American Society of Health-System Pharmacists. Among states allowing telepharmacy, no two have adopted the same practice regulations.

Payers take similarly diverse approaches. Washington and some other states require commercial insurers to reimburse pharmacists on the same basis as physicians, nurse practitioners, and other health care providers. However, most states are silent on payment parity and most commercial payers still balk at paying for nondispensing services, although that could change as the profession continues to push for provider status at state and federal levels.

Medicare does not recognize pharmacists as providers, Kliethermes noted, although the program does reimburse pharmacists up to $150 per month for complex chronic care management. Medicaid reimbursement for pharmacists varies by state.

The biggest financial difference
between a traditional pharmacy and a telepharmacy is the cost structure. The return on investment for a traditional pharmacy depends largely on prescription volume, front-end sales, and pharmacist costs. Telepharmacy lowers the financial bar by sharing pharmacist time across multiple dispensing locations.

According to Barker, reimbursement for remote dispensing is similar to conventional in-person dispensing. The current telepharmacy break-even point is around 70 to 80 prescriptions daily, he said, but the number varies by patient population, prescription mix, payer mix, and other familiar factors.

On the cost side, telepharmacy requires more video hardware than conventional pharmacy to facilitate real-time pharmacist monitoring and conversations, but the cost of off-the-shelf hardware is low—and falling. But best practices, and in many cases state regulations, call for off-site storage of all video and still images from both the remote telepharmacy site and the supervising pharmacist, which increases cloud storage costs.

Telepharmacy software providers typically charge an activation fee and monthly use fees, Barker added. The total cost is roughly equivalent to having a pharmacist on site 1 day per week. Telepharmacy providers should expect to pay for the best technicians available.

“You absolutely need rock star pharmacy technicians [in telepharmacy] because they have a higher level of responsibility and visibility in telepharmacy,” Barker said. “You need good problem solvers who can think on their feet and you need a high level of trust. When you have a telepharmacy, the technician is the public face of the pharmacy.”

Getting paid for virtual clinical services can be as challenging as payment for face-to-face clinical services, Kliethermes said. Medicare reimburses pharmacists for telehealth complex chronic care management. One pharmacy provider, Tabula Rasa HealthCare, is being reimbursed under PACE, the federal Program of All-Inclusive Care for the Elderly, which covers frail older adults who are often eligible for Medicare and Medicaid. However, Medicare payments to pharmacists are more the exception than the rule.

“Because Medicare does not recognize pharmacists as providers, it limits reimbursement regardless of the applicable practice act,” she said. “That makes reimbursement challenging because not all of the Medicare telehealth codes are applicable to pharmacists.”

Technicians are also part of the clinical service and revenue mix. A growing number of states allow pharmacy technicians to administer point-of-care tests, immunizations, specimen collection, and other clinical services under pharmacist supervision, Barker noted.

“All of those clinical services can happen safely and effectively through the telepharmacy model,” he said. “At this point, the model is proven and works well. Telepharmacy is letting us extend the reach of our pharmacists and their clinical services. Pharmacists are delivering the same care they provide in a traditional community pharmacy; they’re just delivering it in a different model.”

For references, visit drugtopics.com.

The 3 T’s: Telemedicine, Telehealth, or Telepharmacy?

There are no universal definitions for the remote delivery of health care, which complicates the conversation. However, pharmacists can provide all 3 services, said Mary Ann Kliethermes, PharmD, director of medication safety and quality for the American Society of Health-System Pharmacists. “There is crossover in all of these terms and practice models,” she said, “and they can all apply to pharmacy and pharmacists. There is a growing collection of services you can provide remotely under different labels and models.”

Telemedicine is a broad catchall for any remote clinical services.

Telehealth is the “use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health, and health administration,” according to the US Department of Health and Human Services. Telehealth and telemedicine cover the entire range of pharmacist clinical services, from intensive counseling to medication review, chronic care or diabetes management, smoking cessation, travel health, immunization counseling, and more.

Telepharmacy is “the provision of pharmacist care by registered pharmacists and pharmacists... through the use of telecommunications... to patients or their agents at distances...” in the National Association of Boards of Pharmacy Model State Pharmacy Act and Model Rules. Telepharmacy focuses more on dispensing, typically using live video to link the pharmacist, the remote dispensing site, and the patient.

For More Information

The COVID-19 pandemic transformed telehealth and telepharmacy from an interesting, maybe useful approach to health care into a must-have service to deliver personalized care with minimal in-person contact. The state pharmacy board is the first stop for pharmacists interested in telepharmacy because not all states allow the practice. State pharmacy associations are another vital source for local guidance.

National associations can add best practices, revenue opportunities, billing considerations, workflow, metrics, and other research-based information. For links to these resources, scan the QR code or visit drugtopics.com.
So much has changed over the past few decades in how we consume media. The advent and proliferation of social media, subscription-based news outlets, and the ubiquitous presence of the internet have created an ultrafragmented audience for anyone marketing a product or service. Amid all this “noise,” it has become increasingly difficult to know when, where, and how to get the attention of potential customers. Do I need a website and social media, or is only one sufficient? The functions of a website and of social media platforms are different. Independent pharmacies should have both to ensure adequate information about the business is available online.

Which comes first? Creating a social media account is less involved but building a website allows for a comprehensive digital storefront—a home base if you will—and provides a destination for all other messaging to point. Many free builder tools (GoDaddy, Wix, and Mailchimp, for example) provide easy-to-use templates for simple websites. Good sites will include a welcome message to visitors, bullet points on what sets your business apart from other pharmacies, contact information, a clear photo of the building, and an introduction to your lead pharmacist.

Remember, people want to do business with people, not “brands.” Once your website is in place, social media begins to serve an important function. No matter which platform you choose, social media is a terrific way to add personality to your brand and connect with your audience in a more conversational way. Facebook and Twitter provide simple avenues to disseminate health care news and updates in a timely manner. With social media, your audience will want to talk to you. Be careful not to provide any diagnostic health care advice or individualized feedback to a patient on social platforms. Keep those conversations between you and patients inside your pharmacy.

How do I choose the right social media platform? First, identify your customer. If you’re located in a bustling college town, you may be successful with a presence on Instagram or TikTok—but in a market with an older audience, TikTok may be an unwise choice. Most businesses should at least have a Facebook page; consumers tend to use Facebook to find simple information like store hours, location, and information on promotions. A Facebook page also provides a consistent opportunity for businesses to interact and maintain a presence with potential customers.

What’s next? Identify your objective before you start. Determine what you want to accomplish in 1 year, then break that down into smaller pieces. Are you looking for new patients or customers, or would you like a higher spend in your store from existing patients? Are you hoping to expand point-of-care services or frontline retail options to generate more revenue? Each of these goals requires a different marketing approach. Review and assess your progress toward the goal on a monthly or quarterly basis. Don’t wait until the end of the year to “pass” or “fail.”
Decide on your primary message. What is your brand promise? What sets your business apart from other pharmacies? Marketing materials must be consistent and include your main message. Each touchpoint with your customers contributes to your pharmacy’s unique voice in the marketplace, and this reinforcement helps build a clear, consistent reputation across your audience.

Delegate marketing responsibilities. Build the effort into standard daily or weekly pharmacy operations. Whether you choose to do the work yourself or with staff inside your pharmacy, or you contract with a third-party marketing agency, consistency is key. Inconsistent marketing efforts are rarely successful and typically end up being a waste of valuable resources. Choose someone who has an existing interest and ability to engage in these activities regularly to handle the duties.

Start small. Choose simple, measurable initiatives to get started. Once you get comfortable with your public messaging and learn what can be measured, expand from there. Ideally, work up to having 2 or 3 channels activated in 1 marketing campaign.

My budget is limited. How do I know this is working? In our current age of technology, there are so many tools available to measure the effectiveness of a campaign, especially on social media. Marketers can measure clicks, views, shares, and comments to see what type of content resonates with the audience. Most marketing platforms include tools built into their systems, making these metrics highly visible and easy to understand. Once you have insight into the content that is driving the most response, it becomes easier to identify where to allocate resources most effectively.

Think outside the box. The most cherished characteristics of an independent pharmacy are the personal service and relationships built between staff and patients. To build on this foundation, pharmacies can and should be asking satisfied patients for positive online reviews. Many consumers consult the internet before choosing to do business with a company. If your pharmacy has an abundance of happy customers recommending your store online, that is a great way to cultivate testimonial “marketing” without spending anything.

Be your best advocate. A small business should never be the community’s best-kept secret. Every marketing initiative is a conversation with 1 individual at a time, even when communicating to a much larger audience. The enthusiasm that brought you to—and that keeps you going in—the independent pharmacy space is what makes you special in your community. Communicate your passion in an authentic, consistent way and you will be primed for success.

Ginny Langbehn is director of marketing and corporate communications at American Associated Pharmacies (AAP), one of the nation’s largest cooperatives for independent pharmacies.
Public Health and Pharmacy Intersect, Providing Opportunities

Pharmacists are making waves in public health practice. By Aine Cryts

Throughout much of United States history—and certainly until the 1950s—the community drugstore served as a “primary gathering place—a hangout for school kids and a social center for adults—all drawn there by the sweet confections of the soda fountain,” reported the Chicago Tribune in 1985.1

The neighborhood pharmacy’s role as a gathering spot also firmly placed the pharmacist as the most accessible health care provider, explained Mitch Rothholz, RPh, chief of governance and state affiliates and executive director at the American Pharmacists Association (APhA). In fact, a 2022 study revealed patients go to their community pharmacies “almost twice as often as they visit their physicians or other [qualified health providers].”2

Pharmacists have helped community members with public health challenges throughout the history of the United States, Rothholz said. Some of the most pressing public health challenges today include chronic diseases, prescription drug overdoses, vaccine access, and cigarette smoking and vaping, per the American Public Health Association.3

In addition, over 400,000 pharmacists and over 100,000 pharmacy technicians are trained to administer vaccinations “across the life span,” Rothholz said. “Our limitations with [vaccinations are associated with] state laws and regulations and what payers are willing to pay.”

Pharmacists are already engaged in public health efforts when they’re testing patients for influenza, strep throat, or sexually transmitted diseases, or facilitating smoking cessation programs, he explained. However, the challenge is demonstrating the value of these services to health plans and getting employers to support these programs financially. Rothholz explained, adding that pharmacists are increasingly “getting outside the 4 walls of the pharmacy.”

Ensuring Community Pharmacists Could Administer the COVID-19 Vaccine

The ability for pharmacists to administer the COVID-19 vaccine was certainly helpful at the peak of the pandemic, which is soon projected to result in the deaths of 1 million US residents. As of February 9, the CDC reported that over 229.2 million doses of the COVID-19 vaccine were administered and by retail pharmacies across the country.4

Approximately 2400 miles away, in Delano, California, Komoto Pharmacy has administered over 11,000 COVID-19 vaccines since early 2021. But it was during the fall of 2020 that Brian Komoto, PharmD, president and CEO of Komoto Pharmacy, realized community pharmacists wouldn’t be able to administer the vaccine that would soon become available to adults across the state.

It took 3 months for Komoto to navigate and execute a pathway to work with the federal and state government to ensure community pharmacists could administer the COVID-19 vaccine. An important milestone in that journey was reached when California Governor Gavin Newsom issued an executive order that allowed pharmacists, pharmacy technicians, dentists, and nurses to administer the vaccine beginning January 27, 2021.6

Since then, Komoto Pharmacy has provided vaccinations at dozens of farms, 6 schools, and multiple vaccination sites located in nearby municipal gathering places across their agricultural community.

Earlier this year, APhA awarded Komoto the Daniel B. Smith Practice Excellence Award, in part because of his establishment of the Komoto Family Foundation, which is dedicated to promoting wellness and health equity in partnership with under-resourced communities.7 The foundation—which helps improves access to pharmacist-provided health care services—
has, according to APhA, saved patients over $3.7 million since it was founded in 2013.

Exposing Pharmacy Students to Public Health

Hoai-An Truong, PharmD, MPH, started volunteering in the public health field 20 years ago. Since then, he’s been involved in blood pressure screening and diabetes risk assessment, as well as being deployed by the Federal Emergency Management Agency (FEMA) at COVID-19 vaccine sites in both Norfolk, Virginia, and Las Cruces, New Mexico.

In May 2021, Truong was a volunteer vaccinator with 2 of his students at the University of Maryland Eastern Shore in Princess Anne, where he serves as a professor of pharmacy administration and public health. Vaccination sites in Norfolk and neighboring city, Hampton, Virginia, included churches, high schools, and jails.

“As members of the pharmacy profession, we contributed to the vaccine preparation, quality control, and administration of the 2-step [Pfizer-BioNTech] vaccine, as well as the single-dose counterpart produced by Johnson and Johnson,” wrote Truong, along with students Randi Wright and Michelle Yang, in an article published by the university.

During their FEMA deployment, the trio spent their days tackling vaccine hesitancy and trypanophobia (fear of the needle) by “providing education and demonstrating compassion,” Truong, Wright, and Yang wrote.

Truong remembers a time when he was able to convince a COVID-19 vaccine-hesitant husband to accept the vaccine. “The husband and wife came together to get the vaccine [for the wife]. The husband came to be supportive, but he was ‘on the fence,’” he said.

Instead of lecturing the couple, Truong thanked them for getting vaccinated and told them, “You’re doing this for your family, your community, and for me, as a health care professional. You’re protecting me and the rest of [your community].”

His advice for putting a patient at ease about the vaccine is straightforward: Never prepare the vaccine vial in front of the patient, minimize their anxiety, and distract them. One idea is to ask, “What are you doing for dinner tonight?” Truong said.

In addition to his teaching and public health activities, Truong wrote a book called *The Pharmacist in Public Health: Education, Applications, and Opportunities*, with coauthors James Bresette and Jill Sellers. Published in 2010, the book covers topics such as the development and mission of pharmacy in the United States Public Health Service, medication therapy management as a way to improve public health, telehealth challenges and opportunities associated with public health pharmacy, and strategies and opportunities for students’ involvement in public health.

What keeps Truong engaged in public health—particularly in the areas of disaster services and emergencies—is that “so much goes into planning,” he said. “If [the planning] is done well, it’s virtually never seen. What is seen are the people doing the work at the vaccination site or outside the home of a person who [has] just lost everything in a fire or a natural disaster.”

For references, visit drugtopics.com.
The past 2 years have been quite the roller-coaster ride for health care. Although workforce challenges existed previously, the COVID-19 pandemic has shined a spotlight on health systems labor and workforce needs and the critical role of pharmacy in the care team.

Challenges
Let’s start with the elephant in the room: How has the pandemic impacted health system pharmacy workforces? There is no doubt the pandemic has stressed the nation’s workforces, but health care workers have felt the brunt of that stress. The volume of patients being cared for has changed drastically. Cancelled procedures and avoidance of care have led to layoffs and furloughs, whereas surge periods have led to an influx of higher acuity patients, requiring treatment in new locations, filling of ambulatory care gaps, and pulling out all stops for additional staff.

New or expanded services have also led to pharmacy-focused efforts to support new treatments, vaccinations, prophylaxis, and changing sites of care to telehealth and home infusion. Overall, this was positive, reflecting the importance of pharmacy. However, drug shortages and recalls, compounded during the pandemic added insult to injury.

This was positive overall and reflects the importance of pharmacy. That drug shortages and recalls were compounded during the pandemic added insult to injury.

The result of these challenges is a negative impact on the mental health and well-being of the workforce, leading to higher levels of burnout. This, plus the additional dynamics of the pandemic, has resulted in increased resignations. Although specific figures are not available for pharmacy, the American Hospital Association reported that job postings for allied clinical staff have increased by 41% between January 2020 and January 2022.

Recruitment and retention are top concerns for health system pharmacy leaders, with technician staff shortages representing the biggest concern. This is a multifaceted problem that goes well beyond burnout that will require a multipronged approach.

Additional challenges not related to the pandemic include the pharmacy enterprise scope, workforce skill mix, and pharmacy labor metrics. The pharmacy enterprise describes the broad scope of health system pharmacy services, ranging from acute...
### TABLE 2. ASHP FOUNDATION PHARMACY FORECAST HIGHLIGHTS, 2020–2022

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<tr>
<th>ASHP FOUNDATION PHARMACY FORECAST 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy education and workforce</td>
</tr>
<tr>
<td>1. Health system leaders must identify and engage with partners in other health systems and educational institutions to provide accredited technician education and training programs that will ensure the availability of an increasingly competent technician workforce.</td>
</tr>
<tr>
<td>2. Health systems must appropriately compensate pharmacists and technicians who possess sterile products certifications to ensure an adequate workforce dedicated to this fundamental pharmacy responsibility.</td>
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<tr>
<td>3. Develop and implement policies and procedures that protect all staff involved in the handling of hazardous medications, including appropriate education, training, and certification of personnel, regardless of the health status of the individual employee.</td>
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<tr>
<td>4. Health systems should collaborate with colleges and schools of pharmacy to develop a range of training options for pharmacists to ensure an adequate supply of staff capable of meeting the future needs of the health care system.</td>
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<thead>
<tr>
<th>ASHP FOUNDATION PHARMACY FORECAST 2021</th>
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<tbody>
<tr>
<td>Pharmacy workforce</td>
</tr>
<tr>
<td>1. Promote recognition of ambulatory care pharmacists as primary care providers within your health system.</td>
</tr>
<tr>
<td>2. Ensure your pharmacy enterprise creates advanced practice pharmacist productivity and revenue generation benchmarks.</td>
</tr>
<tr>
<td>3. Assertively lead your organization in development of ambulatory care operational systems that (a) promote credentialing, billing, coding, and documentation for pharmacist providers; (b) achieve financial sustainability; (c) align with state/federal requirements for prescribing pharmacists.</td>
</tr>
<tr>
<td>4. Create advanced technician roles and leadership positions. Redefine minimum requirements for advanced technician roles to include undergraduate degrees and completion of ASHP-accredited and/or ACPE-accredited education programs.</td>
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<tr>
<td>5. Partner with other disciplines to evaluate outcomes of autoverification adoption.</td>
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<tr>
<td>6. Collaborate with academic partners to address the impact of decreasing pharmacy student numbers on experiential education, shared faculty, and residency programs.</td>
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<tr>
<th>ASHP FOUNDATION PHARMACY FORECAST 2022</th>
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<tbody>
<tr>
<td>Building the foundation of the pharmacy enterprise Assuring workforce capability</td>
</tr>
<tr>
<td>1. Actively partner with colleagues in human resources to identify and prioritize opportunities for innovative scheduling and remote work solutions to assist with recruitment and retention of pharmacists and technicians across the pharmacy enterprise.</td>
</tr>
<tr>
<td>2. Engage with human resources leaders to develop a sustainable career advancement model for pharmacy technicians. This should include perpetual development of advanced pharmacy technician roles and strategies to attract and retain pharmacy technicians.</td>
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<tr>
<td>3. Actively plan and schedule time for pharmacy staff to pursue continuing education and professional development activities (e.g., precepting, leadership, and research) to foster career growth, career development, and a culture of learning.</td>
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<tr>
<td>4. Develop a comprehensive plan by which pharmacists can participate in the design and implementation of remote patient care technology to promote optimal patient outcomes. Engage the C-suite to ensure pharmacy is actively involved in organizational plans for remote patient care implementation.</td>
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<tr>
<td>5. Institute a rolling 7-year technology investment plan that addresses projected contemporary, postpandemic health system pharmacy needs. Engage C-suite leaders in the development and execution of the plan.</td>
</tr>
<tr>
<td>6. Establish strategies and resources for employee resilience and well-being, specifically targeted on mitigation of burnout and feelings of isolation, for pharmacists and pharmacy technicians who are transitioning from traditional in-person work to more permanent remote work.</td>
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</table>

ASHP, American Society of Health-System Pharmacists; ACPE, Accreditation Council for Pharmacy Education.

Source: American Society of Health-Systems Pharmacy
Capacity Analysis

Is your department the right size? Assessing key areas, such as workload and acuity metrics, labor metrics, and benchmarks, are necessary to determine whether we have the right number and skill mix in our workforce. Research published in the American Journal of Health-System Pharmacy provided specific examples of these metrics from a recent capacity analysis at an academic medical center (Table 1). Some of these metrics are overlooked as the workforce is assessed, which can cause strain and reduce engagement. Other organizations, such as the American Nurses Credentialing Center Magnet Recognition Program, have exemplary models for supporting training and professional development. By looking at these organizations, health systems leadership can ensure there is budget for training days, annual competencies, new technologies, and professional development to prevent gaps.

Strategic Wisdom

The health system pharmacy workforce has been a priority topic in several recent publications for the American Society of Health-System Pharmacists (ASHP) Foundation Pharmacy Forecasts and the high-value pharmacy enterprise framework. In addition, the newly formed Health System Strategy Council of the American Pharmacists Association will also address workforce challenges. Tables 2 and 3 include excerpts of the recommendations related to workforce (bolded emphasis the author’s own). These key concepts can be used as a checklist to evaluate whether health systems leadership have implemented these recommendations.

The pandemic has highlighted cracks in our health system pharmacy workforce that can be addressed with systematic capacity analysis, justification of resources, and implementation of strong workforce engagement and development plans. For references, visit drugtopics.com.

### TABLE 3: HIGH-VALUE PHARMACY ENTERPRISE

<table>
<thead>
<tr>
<th>DOMAIN 5—SAFETY AND QUALITY</th>
<th>Topic 5: Special considerations for patient and health care worker safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5a. Implement strategies to support workforce resilience and well-being.</td>
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<table>
<thead>
<tr>
<th>DOMAIN 6—PHARMACY WORKFORCE</th>
<th>Topic 1: Pharmacy education</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1b. Learners at each level of training (eg, IPPE, intern, APPE, PGY1 resident, and PGY2 resident) engage in activities at the highest level of their competence.</td>
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<tr>
<td>6.1c. Interprofessional education occurs at all levels of learner education and training within the health system.</td>
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<tr>
<td>6.1d. Pharmacy residency training programs advance the organization’s patient care model.</td>
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<thead>
<tr>
<th>Topic 2: Pharmacist scope of practice, staffing, and practice model</th>
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<tbody>
<tr>
<td>6.2a. The pharmacist’s scope of practice is as a provider and is continuously expanding.</td>
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<tr>
<td>6.2b. Performance metrics and productivity measures are developed and maintained to ensure appropriate staffing models.</td>
</tr>
<tr>
<td>6.2c. The health system only hires and retains pharmacists competent for top-of-license practice.</td>
</tr>
<tr>
<td>6.2d. Innovative pharmacy positions are created to meet contemporary health care opportunities.</td>
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<tr>
<th>Topic 3: Pharmacy technicians</th>
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<tbody>
<tr>
<td>6.3a. Pharmacy technicians participate in advanced roles in all practice settings to expand the scope of pharmacist practice, promote efficiency, and improve patients’ access to care.</td>
</tr>
<tr>
<td>6.3b. Health systems attract new entrants into pharmacy technician careers and only employ competent technicians that are certified.</td>
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<thead>
<tr>
<th>Topic 5: Professional development</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.5a. Career ladders and other professional advancement programs are used to maximize growth and engagement of pharmacy personnel.</td>
</tr>
</tbody>
</table>

For references, visit drugtopics.com.
FROM ACCESS TO EXPERIENCE, ASEMBIA IS THERE WITH YOU
I frequently remind my fellow pharmacists that their license hangs by a nail on the wall. It is not bolted there; if you are not happy, find yourself a new nail.

Given the current climate of community and hospital practice, I know several pharmacists who will not be looking for a new nail but instead have given up entirely on this profession. The common thread among these colleagues is that they practice community pharmacy, but I am quite confident the same feelings hold true for my brothers and sisters in hospital pharmacy practice. (I would love to hear their stories as well.)

Each of these pharmacists' names have been changed.

Bob: Bob wanted to run heavy equipment, like his father. His father insisted that he go to pharmacy school, which he did. Bob graduated at the top of his class and never worked more than a couple of hours of relief. He loved the bulldozer and the backhoe more than the computer and the counting tray. Because pharmacy was never his passion, we cannot count him among the disgruntled.

Nate: Nate was one of my student pharmacists who had a passion for hospital pharmacy. He practiced in the hospital setting for 7 years. Of all the pharmacists who left the profession, he was truly called to a higher duty: Nate enrolled in the seminary and will be ordained as a priest in the next few years. Sometimes salary, staffing, and satisfaction do not really matter when one hears a higher calling. When we attended morning Mass together, I knew there was something special about him.

Diana: Diana practiced pharmacy for at least 30 years at a grocery store chain. She has been less than pleased for some time with her staffing, management, and environment. She left the profession to take up her passion of baking. She opened a bakery and is extremely satisfied now.

Donna: Donna had an excellent position as a clinical pharmacist. She shared her amazing skills with physicians and nurses, but mostly with patients. Donna and her husband moved away to be closer to family. Although there are numerous opportunities available to her, she would do "anything" to not work in community pharmacy practice; she is happy being a grandma, and I doubt she will reenter community practice.

Jerry: I met Jerry when he worked as a representative for a drug company. He knew his products well and was an asset to his company. Jerry left that company and took a job practicing community pharmacy for 20 years. Although he is a few years younger than me, the demands of management have made him leave the profession to pursue his true passions. He is an avid fisherman and hunter and will change his income stream from pharmacist to taxidermist and maple sugar manufacturer.

Abe: Of all my pharmacist friends and acquaintances, this loss troubles me the most. Abe comes from a family of pharmacists: his mother, father, and cousins are all pharmacists. He has been out of school only 8 years. During the 8 years he practiced, Abe took a newly opened grocery store pharmacy to the top in prescription volume and sales. The metrics, demands of management, and lack of staffing have made him give up on the profession and work for his mother-in-law's health care business. He has never been happier and gets to spend time with his growing family.

Enrollments in pharmacy schools are down and for many schools, waiting lists no longer exist. Thanks to the glut of pharmacists produced by academia and the miserable working conditions that the 4 major chains—"Corner," "Three Letter," "Spark," and "Lefty"—have created, many excellent, seasoned pharmacists have left the profession to be priests, bakers, taxidermists, or maple sugar makers... anything but chain pharmacists.

Feel free to send your management my way. I want to keep those nails covered with satisfied licensed pharmacists.

Peter A. Kreckel, RPh, practices community pharmacy in Lemont Furnace, Pennsylvania.
FD A Approves Treatment for Uremic Pruritis

Korsuva is approved for treating moderate to severe pruritis associated with chronic kidney disease

Kathryn Wheeler, PharmD, BCPS

In August 2021, the FDA approved difelikefalin (Korsuva) for the treatment of moderate to severe pruritis associated with chronic kidney disease (CKD) in adults undergoing hemodialysis. Uremic pruritis is a common problem for patients with CKD, with limited treatment options. Korsuva is the first FDA-approved treatment for this indication. Difelikefalin is a κ-opioid agonist; the exact mechanism of therapeutic effect is unknown.

Two randomized, placebo-controlled trials (KALM-1, NCT03422653; KALM-2, NCT03636269) demonstrated difelikefalin efficacy in adults with moderate to severe pruritis undergoing hemodialysis (n = 851). Participants received intravenous (IV) injections of either placebo or difelikefalin 0.5 mg/kg of dry body weight at the end of each hemodialysis session 3 times weekly for 12 weeks. Those using medications to treat itch prior to the study were allowed to continue treatment with these medications during the trials.

Prior to randomization, participants kept daily records for 7 days to establish the baseline presence and itch intensity. Mean baseline scores were 7.1 and 7.2 in KALM-1 and KALM-2, respectively. Baseline scores were compared with itch intensity scores assessed at week 12 of therapy. Primary end point was the proportion of patients who achieved a 4-point reduction in itch score at week 12.

In KALM-1, 40% of participants vs 21% in the placebo group met the primary end point (a 19% between-group difference; 95% CI, 9%-28%). In KALM-2, 37% of participants (vs 26% placebo) met the end point for a 12% between-group difference (95% CI, 3%-20%).

Major adverse events (AEs) across both trials included diarrhea (9%), dizziness (6.8%), nausea (6.6%), gait disturbances inclusive of falls (6.6%), hyperkalemia (4.7%), headache (4.5%), somnolence (4.2%), and mental status changes inclusive of confusional state (3.3%). These AEs occurred at higher rates in the difelikefalin group vs placebo.

In the treatment group, dizziness and somnolence were generally transient and occurred within the first 3 weeks of therapy. Somnolence was more common in older adults (age 65 and older; 7.0% vs 2.8%, respectively).

Some patients in the treatment group discontinued therapy due to gait disturbances, dizziness, and mental status changes. Concomitant administration of opioids, antihistamines, or centrally acting depressant drugs may increase AEs. Difelikefalin is not recommended for use in patients undergoing peritoneal dialysis or in patients with severe hepatic impairment.

Korsuva is supplied as a clear colorless solution in a single-dose vial; vials should be stored at room temperature. Recommended dose is 0.5 μg/kg of dry body weight/dose. Bolus injection must be administered within 60 minutes of syringe preparation, administered by IV injection into the venous line of the dialysis circuit at the conclusion of each hemodialysis treatment. Administration of the medication during a dialysis session will result in the removal of the drug by the dialyzer membrane. Any unused medication remaining in the vial after a dose has been prepared should be discarded.
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