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*Call or reach out to us by June 30, 2022 to see if your practice qualifies for the complimentary practice analysis.
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Chronic Conditions
Opioid abuse and Naloxone’s role

MedicalEconomics.com

Meet William Baer, D.O.
Family doc and cowboy action shooter
Indication
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information
• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX
• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX
• In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX
• Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
JOHN, 66, MAY BE A CANDIDATE FOR VACCINATION — REFER WITH eRx.

PATIENT STORY:

Who’s in John’s Life?
• His wife and two children
• He has taken a big role in his autistic grandson’s life

Lifestyle:
He always makes time to walk his two dogs

Medical History:
Knee replacement

Interaction with HCP:
Since his recent knee replacement, John started seeing his doctor on a yearly basis, as he is more diligent about keeping his weight down and living healthy

Recommendation Opportunity:
During regular office visit

Recommend SHINGRIX Because:
He doesn’t want shingles to affect any part of his retirement

BY REFERRING PATIENTS USING eRx, YOU CAN STAY INFORMED ABOUT PATIENTS LIKE JOHN

If you’re referring patients to a pharmacy for their SHINGRIX vaccination, refer with eRx. This way, you and your staff may have up-to-date records on every patient you refer. Make sure you’re using all your available tools to help simplify the process in your practice.

See the range of patients to consider for vaccination at ProfilesSHINGRIX.com

Important Safety Information (cont’d)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion

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

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

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SGX.JRNA210079 September 2021
Produced in USA.
BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

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

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

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

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

2.3 Dose and Schedule

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

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

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

5.2 Guillain-Barré Syndrome (GBS)

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

5.3 Syncope

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

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

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

Adults Aged 50 Years and Older

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

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2 involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,645) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 60 to 69 years, and 17,331 (60%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were White (74%), followed by Asian (18%), Black (1.4%), and other racial/ethnic groups (6%); 56% were female.

Solicited Adverse Reactions: In Studies 1 and 2, data on solicited local and general adverse reactions were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., days of vaccination and the next 6 days) in a subset of subjects (n = 4,866 receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%), redness (38%), and swelling (26%); and myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

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

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

<table>
<thead>
<tr>
<th>Local Adverse Reactions</th>
<th>Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>SHINGRIX</td>
<td>Placebo</td>
<td>SHINGRIX</td>
<td>Placebo</td>
</tr>
<tr>
<td>Pain, Grade 3a</td>
<td>n=1,315</td>
<td>n=1,312</td>
<td>n=1,311</td>
<td>n=1,305</td>
</tr>
<tr>
<td>Myalgia</td>
<td>88%</td>
<td>14%</td>
<td>83%</td>
<td>11%</td>
</tr>
<tr>
<td>Headache, Grade 3a</td>
<td>10%</td>
<td>1%</td>
<td>7%</td>
<td>1%</td>
</tr>
<tr>
<td>Redness</td>
<td>39%</td>
<td>1%</td>
<td>38%</td>
<td>2%</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>3%</td>
<td>0%</td>
<td>3%</td>
<td>0%</td>
</tr>
<tr>
<td>Feeling, Grade 3f</td>
<td>0.4%</td>
<td>0.2%</td>
<td>1%</td>
<td>0.2%</td>
</tr>
<tr>
<td>GI</td>
<td>24%</td>
<td>11%</td>
<td>17%</td>
<td>9%</td>
</tr>
<tr>
<td>Grade 3</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).
• 7 days included day of vaccination and the subsequent 6 days.
• Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.
• Placebo was a saline solution.
• Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.
• Grade 3 myalgia, fatigue, headache, shivering, and GI: Defined as preventing normal activity.
• Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as ≥39.0°C/102.2°F.
• GI = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

The incidence of solicited local and general reactions was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

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

(continued on next page)
There were no differences in the proportions of subjects reporting any confirmed or suspected local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (28% and 21%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 reported general adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, 4%, and 4%, respectively) compared with Dose 1 (1.4%, 1.4%, 3%, and 2.4%, respectively).

### Unsolicited Adverse Events

Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the 2 studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 51% and 32% of subjects who received SHINGRIX (n = 14,645) or placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in <1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (4% versus 0.2%), injection site pruritus (2.2% versus 0.2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

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

### Serious Adverse Events (SAEs)

In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3%) or placebo (2.2%) from the first administered dose up to 30 days post-last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and 10.4% of subjects who received placebo from the first administered dose up to 1 year post-last vaccination. One subject (<0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

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

### Deaths

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

### Potential Immune-Mediated Diseases

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

### Dosing Schedule

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

### 6.2 Postmarketing Experience

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

#### General Disorders and Administration Site Conditions

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

#### Immune System Disorders

Hypersensitivity reactions, including angioedema, rash, and urticaria.

#### Nervous System Disorders

Guillain-Barré syndrome.

Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome following Vaccination with SHINGRIX

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of SHINGRIX were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases per 100,000 doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases per 100,000 doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1)] of full prescribing information].

#### 8.2 Lactation

**Risk Summary**

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

#### 8.5 Geriatric Use

**Adults Aged 60 Years and Older**

Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 6,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were aged 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3)] of full prescribing information].

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

### 17 PATIENT COUNSELING INFORMATION

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

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

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

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Eliminating busy work

It’s time to destroy busy work at your medical practice. Granted, this will not be easy.

Year after year, before COVID-19 and after, physicians have rated “administrative burdens” as the most vexing problem they face in their practices. What do we mean by administrative burdens? Prior authorizations, late nights charting in clunky electronic health record (EHR) systems, paperwork related to payer contracts and value-based care. Physicians know what kind of busy work I’m talking about. It’s the kind that leads to burnout, loss of staff, and ultimately reduced revenue.

Steven E. Waldren, M.D., M.S., the vice president and chief medical informatics officer for the American Academy of Family Physicians (AAFP), spoke at the recent HIMSS22 health technology conference, and said administrative burdens were the primary cause of physician burnout.

“Why are they burned out? It’s the amount of administrative work they have to do and the time constraints they have on being able to practice the medicine the way they want to,” he said.

So what can be done about these burdens? Experts have spent decades trying to solve most of them, but there are practical solutions that practices can put in place to help make things work more smoothly. Our cover story this month addresses ideas to confront the major pain points, including EHRs, prior authorizations, documentation and negotiating contracts with payers.

We also have a strong personal finance lineup in this, our April issue. We have a feature that breaks down how physicians can get involved in real estate investing, without the hassles that come with being a landlord. Further, we have a column from our investing expert on how physicians should approach investing in health care stocks, and the pitfalls that often comes with investing in an area where you have some expertise.

As always, we want feedback on how we’re doing. If you have questions, story ideas or anything at all please send a note to our Editorial Director Chris Mazzolini at cmazzolini@mjhlifesciences.com.

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President and CEO
of MJH Life Sciences®
Physician’s Financial News®

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COVID-19 COVERAGE CENTRAL

Medical Economics® editors are covering what you need to know during the ongoing novel coronavirus (COVID-19) pandemic. Our ongoing coverage of COVID-19 features:

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- Tips for physicians to extend the life of N95 respirators.
- Mental health tips for doctors and other providers.
- How physicians can protect themselves from COVID-19.
- Strategies for using telehealth.

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Prescribing Information, including Boxed Warning, for APRETUDE.

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APRETUDE (cabotegravir extended-release injectable suspension) for intramuscular use

The following is a brief summary only; see full Prescribing Information, including Boxed Warning, for complete product information.

WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative injection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

CONTRAINDICATIONS
APRETUDE is contraindicated in individuals: with unknown or positive HIV-1 status; with previous hypersensitivity reaction to cabotegravir; receiving the following coadministered drugs for which significant decreases in cabotegravir plasma concentrations may occur due to uridine diphosphate glucuronosyltransferase (UGT1A1) – Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin; Antimycobacterials: rifampin, rifapentine.

WARNING AND PRECAUTIONS
Comprehensive Management to Reduce the Risk of HIV-1 Infection: Use APRETUDE for HIV-1 PrEP to reduce the risk of HIV-1 infection as part of a comprehensive prevention strategy including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. The time from initiation of APRETUDE for HIV-1 PrEP to maximal protection against HIV-1 infection is unknown. Risk for HIV-1 acquisition includes behavioral, biological, or epidemiologic factors including, but not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Counsel individuals on the use of other prevention measures (e.g., consistent condom use; knowledge of partner(s)’ HIV-1 status, including viral suppression status; regular testing for STIs that can facilitate HIV-1 transmission). Inform individuals about and support their efforts in reducing sexual risk behavior. Use APRETUDE to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment; therefore, care should be taken to minimize the risk of initiating or continuing APRETUDE before confirming the individual is HIV-1 negative. Prior to initiating APRETUDE for HIV-1 PrEP, ask seronegative individuals about recent (in past month) potential exposure events (e.g., condomless sex or condom breaking during sex with a partner of unknown HIV-1 status or unknown viremic status, a recent STI), and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute or primary HIV-1 infection. When using APRETUDE for HIV-1 PrEP, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs. If an HIV-1 test indicates possible HIV-1 infection, or if symptoms consistent with acute HIV-1 infection develop following an exposure event, additional HIV testing to determine infection status is needed. If an individual has confirmed HIV-1 infection, the individual must be transitioned to a complete HIV-1 treatment regimen. Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE in order to reduce the risk of HIV-1 acquisition and the potential development of resistance. Some individuals, such as adolescents, may benefit from frequent visits and counseling to support adherence to the dosing and testing schedule. Potential Risk of Resistance with APRETUDE: There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before or while taking APRETUDE or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1 negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment regimen. Alternative forms of PrEP should be considered following discontinuation of APRETUDE for those individuals at continuing risk of HIV-1 acquisition and initiated within 2 months of the final injection of APRETUDE. Long-Acting Properties and Potential Associated Risks with APRETUDE: Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). It is important that health care providers limit the number of APRETUDE injections per month and monitor for the required every-2-month injection dosing schedule because non-adherence to every-2–monthly injections or missed doses could lead to HIV-1 acquisition and development of resistance. Healthcare providers should take the prolonged-release characteristics of cabotegravir into consideration when APRETUDE is prescribed. Hypersensitivity Reactions: Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE. Administration of cabotegravir oral lead-in dosing was used in clinical studies to help identify participants who may be at risk of a hypersensitivity reaction. Remain vigilant and discontinue APRETUDE if a hypersensitivity reaction is suspected. Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash, or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters, mucosal involvement [oral blisters or lesions], conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, difficulty breathing). Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated for patients with long-acting properties or severe (Grade 3) or fatal (Grade 4) reactions. See the previous section. Hepatotoxicity: Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors. Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated. For information regarding long-acting properties of APRETUDE, see previous section. Depressive Disorders: Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicide ideation or attempt) have been reported with APRETUDE. Promptly evaluate individuals with depressive symptoms to assess whether the symptoms are related to APRETUDE and to determine whether the risks of continued therapy outweigh the benefits. Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions: The concomitant use of APRETUDE and other drugs may result in reduced drug concentration of APRETUDE. See DRUG INTERACTIONS section below for steps to prevent or minimize as possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE.

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 with rates in the clinical trials of another drug and may not reflect rates observed in practice. Clinical Trials Experience in Adults: The safety assessment of APRETUDE is based on the analysis of data from 2 international, multicenter, double-blind trials, HPTN 083 and HPTN 084. Adverse reactions were reported while on blinded study product following exposure to APRETUDE extended-release injectable suspension and oral cabotegravir tablets as oral lead-in. The median time on blinded study product in HPTN 083 was 65 weeks and 2 days (range: 1 day to 156 weeks and 1 day), with a total exposure on cabotegravir of 3,231 person-years. The median time on blinded study product in HPTN 084 was 64 weeks and 1 day (range: 1 day to 153 weeks and 1 day), with a total exposure on cabotegravir of 2,009 person-years. The most common adverse reactions regardless of severity reported in at least 1% of participants in HPTN 083 or HPTN 084 are presented in Table 4. In HPTN 083, 6% of participants in the group receiving APRETUDE intramuscular injection every 2 months and 4% of participants receiving oral TRUVADA (emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF)) once daily discontinued due to adverse events (all causality). Non-injection-site–associated adverse events leading to discontinuation and occurring in >1% of participants were increased alanine aminotransferase with APRETUDE and TRUVADA. In HPTN 084, 1% of participants receiving APRETUDE and 1% of participants receiving TRUVADA discontinued due to adverse events. The most commonly reported adverse event (all causality) leading to discontinuation was increased alanine aminotransferase (<1%) with APRETUDE and TRUVADA. The side-by-side tabulation is to simplify presentation; direct comparison across trials should not be made due to differing trials.

(cont’d on next page)
Apretude_Logo_Icon_Journal_ad_CMYK_Bleed.ai

BRIEF SUMMARY for Apretude (cabotegravir extended-release injectable suspension), for intramuscular use (cont’d)

Table 4. Adverse Drug Reactions* (All Grades) Reported in at Least 1% of Participants Receiving Apretude in Either HPTN 083 or HPTN 084

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>HPTN 083</th>
<th>HPTN 084</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site reactionsb</td>
<td>APRETUDE Every 2 Months (n = 2,281)</td>
<td>TRUVADA Once Daily (n = 2,285)</td>
</tr>
<tr>
<td>Injection site reactionsb</td>
<td>82%</td>
<td>35%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Headache</td>
<td>4%</td>
<td>3%</td>
</tr>
<tr>
<td>Pyrexiae</td>
<td>4%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Fatiguea</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Sleep disordersa</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Nausea</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Flatulence</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Abdominal paing</td>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>&lt;1%</td>
<td>1%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Rasha</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Back pain</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>0</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

*Adverse reactions defined as “treatment-related” as assessed by the investigator, with exception of injection site reactions, where all injection site reactions were reported regardless of causality.

- Participants who received injection: HPTN 083, APRETUDE (n = 2,117) and TRUVADA (n = 2,081); HPTN 084, APRETUDE (n = 1,519) and TRUVADA (n = 1,516).
- Pyrexia includes pyrexia, feeling hot, chills, influenza-like illness.
- Fatigue includes fatigue, malaise.
- Sleep disorders include insomnia, abnormal dreams.
- Abdominal pain includes abdominal pain, upper abdominal pain.
- Rash includes rash, erythema, pruritus, macular, papular, maculopapular.

Injection-Associated Adverse Reactions: Local Injection Site Reactions (ISRs) with Apretude: The most frequent adverse reactions associated with the intramuscular administration of Apretude in HPTN 083 were ISRs. After 20,286 injections, 8,900 ISRs were reported. Of the 2,117 participants who received at least one injection of Apretude, 1,740 (82%) participants experienced at least one ISR, of which a total of 3% of participants discontinued Apretude because of ISRs. Among the participants who received Apretude and experienced at least one ISR, the maximum severity of reactions was mild (Grade 1) in 41% of participants, moderate (Grade 2) in 56% of participants, and severe (Grade 3) in 3% of participants. The median duration of overall ISR events was 4 days. The proportion of participants reporting ISRs at each visit and the severity of the ISRs decreased over time. The most commonly reported ISRs (all causality and grades) in at least 1% of participants who received Apretude and experienced at least one ISR from HPTN 083 are presented in Table 5. The most frequent adverse reactions associated with the intramuscular administration of Apretude in HPTN 084 were ISRs. After 13,068 injections, 1,171 ISRs were reported. Of the 1,519 participants who received at least one injection of Apretude, 578 (38%) participants experienced at least one ISR. No participants discontinued Apretude because of ISRs. Among the participants who received Apretude and experienced at least one ISR, the maximum severity of reactions was mild (Grade 1) in 66% of participants, moderate (Grade 2) in 34% of participants, and severe (Grade 3) in less than 1% of participants. The median duration of overall ISR events was 8 days. The proportion of participants reporting ISRs at each visit and the severity of the ISRs generally decreased over time. The most commonly reported ISRs (all causality and grades) in at least 1% of participants who received Apretude and experienced at least one ISR from HPTN 084 are presented in Table 5.

Table 5. Injection Site Reactions (All Grades) Reported in at Least 1% of Participants who Experienced at Least One Injection Site Reaction (All Causality) with Apretude in Either HPTN 083 or HPTN 084

<table>
<thead>
<tr>
<th>Injection Site Reactions</th>
<th>HPTN 083</th>
<th>HPTN 084</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection Site Reactions</td>
<td>APRETUDE (n = 1,740)</td>
<td>TRUVADA* (n = 724)</td>
</tr>
<tr>
<td>Pain/tenderness</td>
<td>98%</td>
<td>95%</td>
</tr>
<tr>
<td>Nodules</td>
<td>15%</td>
<td>2%</td>
</tr>
<tr>
<td>Induration</td>
<td>15%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Swelling</td>
<td>12%</td>
<td>1%</td>
</tr>
<tr>
<td>Bruising</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Erythema</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Pruritus</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Warmth</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Abscess</td>
<td>&lt;1%</td>
<td>0</td>
</tr>
<tr>
<td>Discoloration</td>
<td>&lt;1%</td>
<td>0</td>
</tr>
</tbody>
</table>

*Placebo injectable suspension: intralipid 20% fat emulsion.

Other Injection-Associated Adverse Reactions: In the HPTN 083 clinical trial, an increased incidence of pyrexia (including pyrexia, feeling hot, chills, influenza-like illness) (4%) was reported by participants receiving Apretude compared with participants receiving TRUVADA (<1%). There were no differences reported in the occurrence of pyrexia between groups in HPTN 084. Vasovagal or pre-syncopal reactions considered treatment related were reported in <1% of participants after injection with Apretude in HPTN 083. None were reported as treatment related by the investigators in HPTN 084.

Less Common Adverse Reactions: The following select adverse reactions (regardless of severity) occurred in <1% of participants receiving Apretude in HPTN 083 or HPTN 084: Hepatotoxicity: Hepatotoxicity. Investigations: Weight increase (see below). Psychiatric Disorders: Depression. Weight Increase: At the Week 41 and Week 97 timepoints in HPTN 083, participants who received Apretude gained a median of 1.2 kg (interquartile Range [IQR]: -1.0, 3.5; n = 1,623) and 2.1 kg (IQR: -0.9, 5.9; n = 601) in weight from baseline. Those who received TRUVADA gained a median of 0 kg (IQR: -2.1, 2.4; n = 1,611) and 1 kg (IQR: -1.9, 4.0; n = 598) in weight from baseline, respectively. At the Week 41 and 97 timepoints in HPTN 084, participants who received Apretude gained a median of 2 kg (IQR: 0.0, 5.0; n = 1,151) and 4 kg (IQR: 0.0, 8.0; n = 216) in weight from baseline, respectively. Those who received TRUVADA gained a median of 1 kg (IQR: -1.0, 4.0; n = 1,131) and 3 kg (IQR: -1.0, 6.0; n = 218) in weight from baseline, respectively.

Laboratory Abnormalities: Grade 3 or 4 post-baseline maximum toxicity laboratory abnormalities for HPTN 083 or HPTN 084 are summarized in Table 6.

(cont’d on next page)
BRIEF SUMMARY for APRETUDE (cabotegravir extended-release injectable suspension), for intramuscular use (cont’d)

Table 6. Laboratory Abnormalities (Grades 3 to 4) in ≥1% of Participants in Either HPTN 083 or HPTN 084

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>HPTN 083</th>
<th>HPTN 084</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>APRENUDE Every 2 Months (n = 2,281)</td>
<td>TRUVADA Once Daily (n = 2,285)</td>
</tr>
<tr>
<td>ALT (≥5.0 x ULN)</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>AST (≥7.0 x ULN)</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Creatine phosphokinase (≥10.0 x ULN)</td>
<td>15%</td>
<td>14%</td>
</tr>
<tr>
<td>Lipase (≥3.0 x ULN)</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Creatinine (≥1.8 x ULN or increase to ≥1.5 x baseline)</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>

ALT = Alanine transaminase, ULN = Upper limit of normal, AST = Aspartate transaminase.

Serum Lipids: Changes from baseline to Month 15 in total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, and total cholesterol to HDL ratio in HPTN 083 and HPTN 084 are presented in Table 7.

Table 7. Fasting Lipid Values, Median Change from Baseline* at Week 57, Reported in HPTN 083 and HPTN 084

<table>
<thead>
<tr>
<th></th>
<th>HPTN 083</th>
<th>HPTN 084</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>APRENUDE</td>
<td>TRUVADA</td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>+1.0</td>
<td>-1.0</td>
</tr>
<tr>
<td>LDL cholesterol (mg/dL)</td>
<td>+1.0</td>
<td>-6.0</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dL)</td>
<td>-0.2</td>
<td>-3.0</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>+2.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Total cholesterol: HDL cholesterol ratio</td>
<td>+0.1</td>
<td>+0.0</td>
</tr>
</tbody>
</table>

*Nearly 60% of participants with baseline data available had Week 57 data available in both arms of both trials. Within each trial, baseline values were comparable among participants receiving APRENUDE and TRUVADA.

Clinical Trials Experience in Adolescents: In adolescents receiving APRENUDE for HIV-1 PrEP, the safety data were comparable to the safety data reported in adults receiving APRENUDE for HIV-1 PrEP.

DRUG INTERACTIONS

Use of Other Antiretroviral Drugs after Discontinuation of APRENUDE: Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). These residual concentrations are not expected to affect the exposures of antiretroviral drugs that are initiated after discontinuation of APRENUDE. Potential for Other Drugs to Affect APRENUDE: Cabotegravir is primarily metabolized by UGT1A1 with some contribution from UGT1A8. Drugs that are strong inducers of UGT1A1 or 1A9 are expected to decrease cabotegravir plasma concentrations; therefore, coadministration of APRENUDE with these drugs is contraindicated. Established and Other Potentially Significant Drug Interactions: Information regarding potential drug interactions with cabotegravir is provided below. These recommendations are based on either drug interaction trials following oral administration of cabotegravir or predicted interactions due to the expected magnitude of the interaction. The information below includes potentially significant interactions but is not all inclusive.

- Anticonvulsants: Carbamazepine, oxcarbazepine, phenobarbital, phenytoin – coadministration is contraindicated with APRENUDE due to significant decreases in plasma concentration of APRENUDE
- Antimycobacterials: Rifampin, rifapentine – coadministration is contraindicated with APRENUDE due to potential for significant decreases in plasma concentration of APRENUDE
- Antimycobacterial: Rifabutin – when rifabutin is started before or concomitantly with the first initiation injection of APRENUDE, the recommended dosing of APRENUDE is one 600-mg (3-mL) injection, followed 2 weeks later by a second 600-mg (3-mL) initiation injection and monthly thereafter while on rifabutin. When rifabutin is started at the time of the second initiation injection or later, the recommended dosing schedule of APRENUDE is 600 mg (3 mL) monthly while on rifabutin. After stopping rifabutin, the recommended dosing schedule of APRENUDE is 600 mg (3 mL) every 2 months.
- Narcotic analgesics: Methadone – no dose adjustment of methadone is required when starting coadministration of methadone with APRENUDE. However, clinical monitoring is recommended as methadone maintenance therapy may need to be adjusted in some individuals

Drugs without Clinically Significant Interactions with Cabotegravir: Based on drug interaction study results, the following drugs can be coadministered with cabotegravir (non-antiretrovirals) or given after discontinuation of cabotegravir (antiretrovirals and non-antiretrovirals) without a dose adjustment: Etravirine, Midazolam, Oral contraceptives containing levonorgestrel and ethinyl estradiol, and Rifampin.

Consult the full Prescribing Information for potential drug interactions; this list is not all inclusive.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to APRENUDE during pregnancy. Healthcare providers are encouraged to register individuals by calling the Antiretroviral Registry (APR) at 1-800-258-4263. Risk Summary: There are insufficient human data on the use of APRENUDE during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage. While there are insufficient human data to assess the risk of neural tube defects (NTDs) with exposure to APRENUDE during pregnancy, NTDs were associated with dolutegravir, another integrase inhibitor. Healthcare providers should discuss the benefit-risk of using APRENUDE with individuals of childbearing potential or during pregnancy. Cabotegravir use in pregnant women has not been evaluated. APRENUDE should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus. The APR has been established to monitor for birth defects following prenatal exposure to antiretrovirals. The rate of miscarriage is not reported in the APR. The background rate for major birth defects in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP) is 2.7%. The estimated background rate of miscarriage in clinically recognized pregnancies in the U.S. general population is 15% to 20%. The APR uses the MACDP as the U.S. reference population for birth defects in the general population. The MACDP evaluates women and infants from a limited geographic area and does not include outcomes for births that occurred at <20 weeks gestation. In animal reproduction studies with oral cabotegravir, a delay in the onset of parturition and increased stillbirths and neonatal deaths were observed in rats after oral gavage and in a rat pre- and postnatal development study at >28 times the exposure at the recommended human dose (RHD). No evidence of adverse developmental outcomes was observed with oral cabotegravir in rats or rabbits (>28 times or similar to the exposure at the RHD, (cont’d on next page)
BRIEF SUMMARY for APRETUDE (cabotegravir extended-release injectable suspension), for intramuscular use (cont’d)

respectively) given during organogenesis (see Data). Clinical Considerations: Cabotegravir is detected in systemic circulation for up to 12 months or longer after discontinuing injections of APRETUDE; therefore, consideration should be given to the potential for fetal exposure during pregnancy. Data: Human Data: Data from a birth outcome surveillance study in Botswana showed that dolutegravir, another integrase inhibitor, was associated with increased risk of NTDs when administered at the time of conception and in early pregnancy. Data from clinical trials are inconsistent for ad interim risk with cabotegravir. Animal Data: Cabotegravir was administered orally to pregnant rats at 0, 0.5, 5, or 1,000 mg/kg/day from 15 days before cohabitation, during cohabitation, and from Gestation Days 0 to 17. There were no effects on fetal viability when fetuses were delivered by caesarean, although a minor decrease in fetal body weight was observed at 1,000 mg/kg/day (>28 times the exposure in humans at the RHD). No drug-related fetal toxicities were observed at 5 mg/kg/day (approximately 13 times the exposure in humans at the RHD), and no drug-related fetal malformations were observed at any dose. Cabotegravir was administered orally to pregnant rabbits at 0, 30, 500, or 2,000 mg/kg/day from Gestation Days 7 to 19. No drug-related fetal toxicities were observed at 2,000 mg/kg/day (approximately 0.7 times the exposure in humans at the RHD). In a rat pre- and postnatal development study, cabotegravir was administered orally to pregnant rats at 0, 0.5, 5, or 1,000 mg/kg/day from Gestation Day 6 to Lactation Day 21. A delay in the onset of parturition and increases in the number of stillbirths and neonatal deaths by Lactation Day 4 were observed at 1,000 mg/kg/day (>28 times the exposure in humans at the RHD); there were no alterations to growth and development of surviving offspring. In a cross-fostering study, similar incidences of stillbirths and early postnatal deaths were observed when rat pups born to cabotegravir-treated mothers were nursed from birth by control mothers. There was no effect on neonatal survival of control pups nursed from birth by cabotegravir-treated mothers. A lower dose of 5 mg/kg/day (13 times the exposure at the RHD) was not associated with delayed parturition or neonatal mortality in rats. Studies in pregnant rats showed that cabotegravir crosses the placenta and can be detected in fetal tissue. Lactation: Risk Summary: It is not known if cabotegravir is present in human breast milk, affects human milk production, or has effects on the breastfed infant. When administered to lactating rats, cabotegravir was present in milk (see Data). If cabotegravir is present in human milk, residual exposures may remain for 12 months or longer after the last injections have been administered. Because of detectable cabotegravir concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of APRETUDE, it is recommended that women breastfeed only if the expected benefit justifies the potential risk to the infant. Data: Animal Data: Animal lactation studies with cabotegravir have not been conducted. However, cabotegravir was detected in the plasma of nursing pups on Lactation Day 10 in the rat pre- and postnatal development study. Pediatric Use: The safety and effectiveness of APRETUDE for HIV-1 PrEP in at-risk adolescents weighing at least 35 kg is supported by data from 2 adequate and well-controlled trials of APRETUDE for HIV-1 PrEP in adults with additional safety and pharmacokinetic data from studies in HIV-1 infected adults who were administered CABENIVA, and in HIV-1 infected pediatric subjects who were administered separate components of CABENIVA in addition to their current antiretroviral therapy. APRETUDE for HIV-1 PrEP is being evaluated in 2 open-label multicenter clinical trials in adolescent individuals. Fifty-nine adolescents have been enrolled. Of these, 54 adolescent participants received one or more injections. In adolescents receiving APRETUDE for HIV-1 PrEP, the safety data were comparable to the safety data reported in adults receiving APRETUDE for HIV-1 PrEP. While using APRETUDE, HIV-1 testing should be conducted prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) and prior to each injection of APRETUDE. Adolescents may benefit from more frequent visits and counseling to support adherence to the dosing and testing schedule. The safety, efficacy, and pharmacokinetics of APRETUDE in pediatric participants younger than 12 years of age or weighing <35 kg have not been established. Geriatric Use: No dose adjustment is required in elderly individuals. There are limited data available on the use of APRETUDE in individuals aged 65 years and older. In general, caution should be exercised in administration of APRETUDE in elderly individuals reflecting greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Renal Impairment: Based on studies with oral cabotegravir, no dosage adjustment of APRETUDE is necessary for individuals with mild (creatinine clearance >60 to <90 mL/min) or moderate renal impairment (creatinine clearance >30 to <60 mL/min). In individuals with severe renal impairment (creatinine clearance <15 mL/min), increased monitoring for adverse effects is recommended. In individuals with end-stage renal disease not on dialysis, effects on the pharmacokinetics of cabotegravir are unknown. As cabotegravir is >99% protein bound, dialysis is not expected to alter exposures of cabotegravir. Hepatic Impairment: Based on studies with oral cabotegravir, no dosage adjustment of APRETUDE is necessary for individuals with mild or moderate hepatic impairment (Child-Pugh A or B). The effect of severe hepatic impairment (Child-Pugh C) on the pharmacokinetics of cabotegravir is unknown. OVERDOSAGE There is no known specific treatment for overdose with APRETUDE. If overdose occurs, monitor the individual and apply standard supportive treatment as required as well as observation of the clinical status of the individual. As APRETUDE is highly bound to plasma proteins, it is unlikely that it will be significantly removed by dialysis. Consider the prolonged exposure to APRETUDE following an injection when assessing treatment needs and recovery.
When identifying promising health care stocks, familiarity bias is not your friend

By Dave S. Gilreath, CFP

Many investors make mistakes because they have familiarity bias — the inclination to invest in companies or industries just because they know something about them.

Familiarity bias can also be negative. If a cardiac surgeon dislikes a certain kind of medical device, he or she might be soured on investing in the manufacturer, regardless of growth prospects.

Naturally, the best way to approach stocks is without any bias. Because health care is likely to be a fruitful sector this year and beyond, a disinclination to invest might mean missed opportunities.

Currently, health care is a split sector. Some companies have hit new recent highs whereas others have descended to new recent lows, so discriminating between them is even more critical. This is a time for discerning stock picking rather than using funds or exchange-traded funds.

A surgeon’s potential bias against a supplier could be particularly disadvantageous these days because medical device and instrument companies are poised for growth as hospitals and surgery centers resume elective procedures suspended during the COVID-19 pandemic. This is happening as many baby boomers are entering their late 60s and needing increasing care — a key factor driving growth.

The increase in surgeries comes at a time when health care is an undervalued sector according to its fair value — a measure of an asset’s estimated true or intrinsic worth. Fair value is different from market price, which could be much higher or lower. According to Morningstar, health care is among the stock sectors that, as of mid-February, had their lowest median price relative to fair value since summer 2020, when the world was in the throes of the pandemic shutdown. (Two other such sectors are industrials and, believe it or not, technology.)

The surgery surge bodes well for companies like Medtronic, a manufacturer of surgical/medical devices. Such supplier companies, which provide surgeons with the metaphorical picks and shovels of their profession, generally are poised for growth, as are some pharma and services companies.

Investing in health care stocks is generally complicated by the sector’s current price bifurcation. As of mid-February, some health care companies — including biotech company AbbVie, pharma company Bristol Myers Squibb and nine care provision and services companies — were at three-month relative highs (with AbbVie at an all-time high). Among the nine were McKesson, AmerisourceBergen and Molina Healthcare.

Meanwhile, other health care
firms — primarily in the life sciences tools and services subsector — were at three-month relative lows. Among these were instrumentation and reagent supplier Thermo Fisher Scientific, medical/industrial conglomerate Danaher and medical data science firm IQVIA.

The sector’s current bifurcation reflects likely investor confusion over its future amid an overall market atmosphere of uncertainty. Uncertainty often means opportunities for investors who can identify stocks with the potential to sail briskly without high risk.

My firm did an analysis designed to precisely achieve that. We started by selecting health care stocks with the lowest downside risk, according to our screens. From the resulting group, we selected those with 12-month trailing price/earnings (P/E) ratios below that of the S&P 500 (24.3) and relatively high projected annual earnings growth over five years, as determined by the average of various analysts’ projections. A low P/E reflects good earnings for the price investors must pay for a stock. This tends to attract investors and drive up price, as does projected high earnings growth. Such stocks can be layups in the basketball game of investing.

The resulting list of lower-risk, low-P/E, high projected earnings stocks included Pfizer, Humana, HCA Healthcare, Anthem, Merck, Cigna and CVS Health. Pfizer led the pack in projected average annual earnings growth with 15.88%, followed by Humana at 13.96%, and HCA Healthcare at 12.14%.

Some stocks in the initial, lower-risk group had even higher projected earnings growth — Danaher with 24% annually and biotech firm Vertex with 30% — but both stocks have trailing 12-month P/Es above that of the S&P 500. So did Medtronic, but with lower projected annual earnings — 9.62%. With the resumption of elective surgeries, Medtronic’s earnings in the first year out of five might be significantly higher than in the next four. Also carrying a high trailing P/E is IQVIA Holdings (62%) but that company has projected average annual earnings growth of 22.31%.

Even if these earnings projections are realized, this is not a guarantee of high price appreciation but it is a highly positive indicator. Other factors affecting price are harder to anticipate — for example, in pharma, a cutting-edge new drug or a clinical trial disappointment can send values up or down in an instant.

Equity prices are subject to the impact of recessions, black swan events like the pandemic recession and, more typically, the vagaries of market sentiment. But the metrics used above are among the best available ways to project performance.

Of course, you cannot benefit from a stock’s long-term performance if you don’t keep your shares long term. Productive investing requires patience.

Medical liability premiums increasing

BY TODD SHRYOCK MANAGING EDITOR

An American Medical Association analysis has found that medical liability premiums have surged over the past three years. The prevalence of increases between 2019 and 2021 has not been seen in almost 20 years.

The analysis showed that the share of medical liability premiums with year-to-year increases was somewhat stable between 2010 and 2018. The recent period of upward volatility began in 2019 when the proportion of premiums that increased was about 27%, almost double the rate from 2018.

In 2020 and again in 2021, roughly 30% of premiums increased.

“The medical liability insurance cycle is in a period of increasing premiums, compounding the economic woes for medical practices that struggled during the past two years of the pandemic,” said AMA President Gerald E. Harmon, M.D., in a statement. “The increase in premiums can force physicians to close their practices or drop vital services. This is detrimental to patients as higher medical costs can lead to reduced access to care.”

Twelve states reported double-digit premium increases in 2021. Illinois led all states with the largest proportion (58.9%) of premiums that increased 10% or more, followed by West Virginia (41.7%), Missouri (29.6%), Oregon (20%), South Carolina (16.7%), Idaho (11.1%), Kentucky (7.4%), Delaware (6.7%), Washington (6.7%), Michigan (5.4%) Texas (4.9%), and Georgia (3.7%). The size of the largest premium increase in these states ranged from 35.3% in Illinois to 10% in Idaho and Washington.

“Insurers started raising premiums in response to deteriorating underwriting results, lower loss reserve margins, and lower returns on investment,” according to actuaries cited by the AMA analysis. Thus, actuaries “expected that insurers would sustain or even push for higher premiums in 2021.”

The analysis also found major differences in premiums by location. For example, in 2021 some obstetricians and gynecologists faced base premiums ranging from $49,804 in Los Angeles County, California, to $215,649 in Miami-Dade County, Florida.

The surge in increasing premiums largely coincided with the pandemic, but the analysis noted that the long-term effects of the pandemic are still unknown and it appears base premiums have not been affected for now.
Tim Travis is the CEO/CIO and founder of T&T Capital Management, an investment advisory located in Orange County, California. T&T utilizes a deep value investment approach and offers customized portfolio management for clients across the country. The firm is celebrating its 10th anniversary this year and Travis has been in the investment business for nearly 20 years. Seeking Alpha (SA) sat down with Travis to discuss why he also researches the bearish side for potential long ideas, how/why he uses options and why persistence is an undervalued investing characteristic.

SA: Walk us through your investment decision making process. What area of the market do you focus on and what strategies do you employ?

TRAVIS: Our investment process is focused on maximizing risk-adjusted returns. We begin by trying to identify securities that trade at large discounts to intrinsic value to ensure an adequate margin of safety and create strong upside potential. When we have narrowed down our favorite opportunities, we look at how best to capitalize on them. This often means buying the equity, or perhaps the debt is the better play. It can also mean a more conservative and income-generating strategy such as cash-secured puts or covered calls. This is where the customization of the portfolio comes into play and taking into consideration client risk tolerances and investment objectives.

We do not focus on any one area of the market, but usually we are attracted to areas that are temporarily out of favor, as we tend to find more attractive investment opportunities in those areas. One of the benefits of having been in the business for a long time now is that we are constantly expanding our circle of competence to other industries and companies. Our knowledge of financial stocks is an advantage, but we have invested and had success across a broad spectrum of industries thankfully.

SA: Do you think there’s an edge from “time arbitrage” (a longer holding period)? Is this an edge that will never be competed away? Are there any specific lessons you’ve learned from holding (and intensively following) a stock for years?

TRAVIS: I absolutely think there is time arbitrage from holding stocks over a longer period of time. Undervalued stocks are often priced cheaply because of difficult short-term conditions. It is uncomfortable to buy stocks when you know the next few quarters are likely to be disappointing, due to a challenging economic environment or whatever the case may be. I think being a truly long-term investor is tougher sale for Wall Street, and an even harder practice to employ psychologically, so I do think it is a durable competitive advantage.

Following a stock for years is enormously beneficial. You get a good feel for management and how they react to challenges and opportunities. Generally, the warts of the business emerge over the microscope of time. Sometimes, as we saw last year, stock prices will drop to truly nonsensical prices on businesses you know deeply, allowing you to bet big and with conviction. ALY Financial (NYSE:ALLY) was a great example of that. The stock traded down from the $30’s to less than $10 due to C-19/lockdown fears, which implied losses far greater than seen during the Great Recession. I couldn’t justify the price whatsoever, which meant buying big and taking advantage of that dip. Now the stock trades in the mid $50’s, and I still wouldn’t be shocked to see a big bank buy it if they could clear the regulatory hurdles, but I no longer see the clear and obvious margin of safety and upside potential that it had before.

SA: How do you use management guidance and investor presentations in your analysis? Can you give an example?

TRAVIS: Rarely does anyone know the business better than management, so I certainly use their guidance and investor presentations in my analysis. I don’t focus on any one quarter, but instead look at how they evolve over time. This includes inves-
tor conferences where the investment bank conducting it might target specifics areas of the business such as technology, or drug development etc. Over time the mosaic comes together. Does management deliver on their forecasts? Are they overly promotional? Is there a lot of management turnover? ALLY is a great example of a management team that has regularly beaten its forecasts and delivered on its goals, while not being overly promotional. That gives you a lot of confidence, especially when they are dealing with a recessionary environment. Other companies such as Cleveland-Cliffs (NYSE:CLF) and Assured Guaranty (NYSE:AGO) have also been very solid in how they have publicly communicated with investors. The Cliffs earnings calls are usually my favorite due to the CEO’s style and his ability to deliver on what he says.

**SA:** If you own a stock (and/or are thinking about buying it), do you research the bearish side? If so, how do you separate the legitimate from the not so legitimate bearish arguments and determine if it’s already priced in? Have you ever exited a long position (or not bought in the first place) after reading a persuasive bearish thesis?

**TRAVIS:** I absolutely will research the bearish thesis, as I think one would be foolish not to. A great example of that was David Einhorn’s bearish case on the stock of Assured Guaranty. Most of the argument was based on innuendo and overly pessimistic projections on future losses that didn’t line up with my analysis whatsoever. I had seen current AGO management be overly conservative in its RMBS loss reserves during the financial crisis. I’d seen them accurately reserve for billions in recoveries from rep and warranty litigations following the financial crisis. Now we are seeing that the company is at least fully reserved for Puerto Rico recovery from ridicule after the tough time he experienced during the financial crisis, to becoming a star once again. Persistence is an undervalued characteristic.

**TRAVIS:** We use options as a tool to generate income, reduce risk, and to instill disciplined selling principles. We don’t speculate with them. For the last few years, we have invested in the common stock of CLF, usually buying on dips or selling puts on the stock. From time to time, we’ve been exercised on those puts, and we’d then sell calls way out of the money at prices that we were willing to sell the stock at. With the recent surge in steel and iron ore prices, CLF has run away from us and we’ve sold our stock, despite still loving the company and the management team. We would be willing buyers at cheaper levels though, so we’ve sold puts throughout the year and taken advantage of the relatively high premiums available. Until recently, we were getting 7-8% returns, or midteen returns annualized selling $10 puts on CLF, despite the fact the stock was trading around $20 per share. Surely, if the stock rallies to $30, we’d have done better simply buying stock, but it is a cyclical business and we are concerned with the overall market levels, and for us this is just a very attractive risk-reward opportunity. When you compare this risk-reward versus high-yield bonds for instance, I’d take my chances with selling the puts as we’d be happy to own the stock if it were to drop to those levels and retain the upside from there.

**SA:** How do you use options on an individual and/or portfolio level? Can you give an example? What are the risks with this strategy?

**TRAVIS:** All of my investing role models communicate openly and honestly with their investors. Nobody can control the outcome, but you can control your process, work ethic, and the integrity at which you conduct business. We showcase that on our blog and our newsletter, and our articles such as those posted on Seeking Alpha. One lesson I’ve learned with experience though is to go your own way. Riding the coattails of other investors’ ideas, without doing your own deep dive into the company is a mistake in my estimation. By the time you hear what stocks funds that you respect are buying, the information and opportunity can often be stale, or incomplete. I respect investors such as Bill Miller that have been able to really expand their circle of competence and recover from ridicule after the tough time he experienced during the financial crisis, to becoming a star once again. Persistence is an undervalued characteristic. »

**SA:** What are several key lessons learned from your investing role models? Can you discuss how you applied one (or more) of them?
A physician’s hopes for 2022

As 2022 moves along, I think it is time to take stock of where we have been and where we are going. As I reflect on the difficulties of the past two years, I find reason for optimism. First, our health care system has been stretched to the breaking point but was held together by the dedication of an amazing workforce. The struggles of this pandemic have clearly illustrated our weaknesses. As the grip of COVID-19 lessens, I am hopeful we can honestly discuss how to be better prepared next time and fix our health care system flaws.

Such conversations are already beginning at the local level. Maybe these collaborative discussions will trickle up to policymakers. It is often in times of struggle that we find the will to make changes for the better.

I am hopeful that preparation for the next public health emergency involves not just our public health institutions and hospitals but also the rest of the health care workforce, those closest to the patients and their communities. Primary care practices, local pharmacies, nursing homes and emergency medical services, for example, all need to be part of any comprehensive response system.

I am hopeful that the power of telemedicine will be retained and permanently reimbursed by payers at the same level as in-person visits, so that primary care physicians and other providers can use it to expand access, convenience and continuity for their patients. I am hopeful that we will begin to address our country’s mental health needs and recognize that mental health services are key primary care services and belong integrated in our primary care system.

I am hopeful that we will evaluate any improvements in outcomes promised by value-based contracting and will strive to simplify and standardize the rules and metrics of value-based care. While we’re at it, let’s look at the impact of consolidation and venture capital on our health care system.

I am hopeful that the growing call for increased investment in primary care will be heeded. We need payment improvements to support rural physicians and independent practices because these practices are a vital access point for many underserved populations and communities.

I am hopeful that the call for more investment in primary care will bring a significant increase in primary care residency positions and incentives for medical students to choose primary care as a career. I am hopeful that the need for more primary care will lead to discussion of the ideal mix of primary care physician, physician assistant and nurse practitioner resources needed in this country and that we ensure adequate training and standard certification of all clinicians. There is also a need for transparency surrounding the credentials of each type of primary care clinician seeing patients. The public has the right to know the training and credentials of any professional providing them service.

I am hopeful we will address the needs of our elderly and begin to make improvements that support patients growing old gracefully.

Finally, am I hopeful or just wishful? I am hopeful because I see in our new residents and young graduates a passion for service, energy and professionalism that will rise above the politics and business of medicine that often get in the way of true change. Here’s to 2022 being the year that we begin to make significant strides in improving the U.S. health care system.

L. Allen Dobson Jr., M.D., FAAFP, is a family physician and editor-in-chief of Medical Economics®.
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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

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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, piloerection, 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 hypertensive 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.

  Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated an acute withdrawal syndrome. In some patients, there was aggressive behavior upon abrupt reversal of an opioid overdose. Abrupt postoperative reversal of opioid depression after using naloxone hydrochloride may result in nausea, vomiting, sweating, tremulousness, tachycardia, hypotension, hypertension, seizures, ventricular tachycardia and fibrillation, pulmonary edema and cardiac arrest. Death, coma and encephalopathy have been reported as sequelae of these events. These events have primarily occurred in patients who had pre-existing cardiovascular disorders or received other drugs that may have similar adverse cardiovascular effects. Monitor these patients closely in an appropriate healthcare setting.

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In two pharmacokinetic studies, a total of 47 healthy adult volunteers were exposed to a single dose of KLOXXADO™, one spray in one nostril.

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**References**


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Physicians, are you ready for a ransomware attack?

by Chris Mazzolini Editorial Director

Ransomware has never been a more serious threat for health care organizations, even small medical practices. So what should be done about it? Is it possible to defend yourself? Are there insurance products that can help protect your business in the event of a breach? To discuss these issues, Medical Economics sat down with Peter A. Halprin, Esq., a partner in Pasich LLP’s New York office who specializes in complex insurance coverage matters in relation to cybercrime. The transcript below was edited for length and clarity.

Medical Economics® (ME): Let’s put the ransomware issue into context. How big of a problem is it in health care?

Peter A. Halprin: It is a massive problem. We’re talking about billions of dollars in impacts. And I think the average cost of a breach tends to be around $2 million, with about 10% of that being ransomware payments, and the rest being recovery. As I said, the numbers are going up and up and up. So any number I’d give you is already stale. Unfortunately, the trend is only going to continue.

I think health care is a particularly risky sector in this regard for two reasons. One is there is lots of personal information. So data-rich target, if you will, and the flip side being you’ve got a lot of proprietary systems, you’ve got a lot of older systems that haven’t been updated, don’t get regularly updated. I think in some ways, doctors, like lawyers — they’re focused on their craft. And they’re not necessarily focused on these other things, assuming. Why would anyone do this? Why would anyone target a medical facility or doctor’s office or anything else? And the answer is you’re a target-rich environment and (cybersecurity is) not a priority. So I think health care has continued to be a particularly fertile source for ransomware actors.

ME: How has the COVID-19 pandemic affected cybersecurity?

Halprin: Negatively, for sure. I think that the bad guys have taken advantage of people working from home, people being distracted. It’s very hard to stay focused on your tasks. All of a sudden, you get an email that comes in and it looks very convincing. And I’m telling you, the bad guys are bad. For example, people were getting emails in March of 2020 talking about the cure for COVID-19, or the email looked like it was coming from the World Health Organization or the CDC. So they took advantage of that. Cyber hygiene was definitely down.

I think the other side of it is that the bad actors are targeting specifically vulnerable institutions and organizations. So we saw attacks on vaccine research centers, hospitals, doctor’s offices. For those vulnerable sectors, part of their vulnerability is that it is a matter of life and death. The bad actors take advantage of that vulnerability.

ME: Is being targeted by hackers inevitable?

Halprin: I’m hesitant to say that it’s inevitable because I don’t want people to just throw their hands up, so I don’t love the word. But it is highly, highly probable that there will be an attack or there will be some form of cyber incident or cybercrime involving a health care institution.

So the question is, knowing that there’s that high
HEALTH CARE ORGANIZATIONS WARNED TO GUARD AGAINST CYBERATTACKS BECAUSE OF WAR IN UKRAINE

by Todd Shryock Managing Editor

The Cybersecurity and Infrastructure Security Agency (CISA) of the U.S. government is warning all organizations, including those in health care, to be extra vigilant against cyberthreats because of the war in Ukraine. Russia has launched cyberattacks against Ukraine and the impacts may stretch beyond the region, especially as the United States implements sanctions against Russia.

Every organization must be prepared to respond to disruptive cyber activity, according to CISA, which also asks that all cyber incidents be reported as soon as possible.

CISA recommends all organizations—regardless of size—adopt a heightened posture when it comes to cybersecurity and protecting their most critical assets. Recognizing that many organizations find it challenging to identify resources for urgent security improvements, CISA has compiled a catalog of free services from government partners and industry to assist. Recommended actions include the following:

**Reduce the likelihood of a damaging cyber intrusion**
- Validate that all remote access to the organization’s network and privileged or administrative access requires multifactor authentication.
- Ensure that software is up to date, prioritizing updates that address known exploited vulnerabilities identified by CISA.
- Confirm that the organization’s IT personnel have disabled all ports and protocols that are not essential for business purposes.
- If the organization is using cloud services, ensure that IT personnel have reviewed and implemented strong controls outlined in CISA’s guidance.
- Sign up for CISA’s free cyber hygiene services, including vulnerability scanning, to help reduce exposure to threats.

**Maximize the organization’s resilience to a destructive cyber incident**
- Test backup procedures to ensure that critical data can be rapidly restored if the organization is impacted by ransomware or a destructive cyberattack; ensure that backups are isolated from network connections.
- If using industrial control systems or operational technology, conduct a test of manual controls to ensure that critical functions remain operable if the organization’s network is unavailable or untrusted.

**Take steps to quickly detect a potential intrusion**
- Ensure that cybersecurity/IT personnel are focused on identifying and quickly assessing any unexpected or unusual network behavior. Enable logging in order to better investigate issues or events.
- Confirm that the organization’s entire network is protected by antivirus/antimalware software and that signatures in these tools are updated.
- If working with Ukrainian organizations, take extra care to monitor, inspect and isolate traffic from those organizations; closely review access controls for that traffic.

**Ensure that the organization is prepared to respond if an intrusion occurs**
- Designate a crisis response team with main points of contact for a suspected cybersecurity incident and roles/responsibilities within the organization, including technology, communications, legal and business continuity.
- Assure availability of key personnel; identify means to provide surge support for responding to an incident.
- Conduct a tabletop exercise to ensure that all participants understand their roles during an incident.

CISA says that by implementing the steps above, all organizations can make near-term progress toward improving cybersecurity and resilience. In addition, while recent cyber incidents have not been attributed to specific actors, CISA urges cybersecurity/IT personnel at every organization to review Understanding and Mitigating Russian State-Sponsored Cyber Threats to U.S. Critical Infrastructure. CISA also recommends organizations visit StopRansomware.gov, a centralized, whole-of-government webpage providing ransomware resources and alerts.
probability, how do you address that? You really want to beef up your security, what I call cyber hygiene. It’s protecting your business, it’s making sure that people don’t click those bad links, it’s making sure that you clearly identify when an email comes from an outside source, it’s making sure that sensitive areas in a business are closed off so that people can’t penetrate security.

The second instance can come in the form of limiting access. If someone’s able to access your account, then they can get no further than what you can access. It’s that kind of internal security.

**ME: What about cyber liability insurance?**

**Halprin:** Yes, the third layer is cyber insurance. So you get insurance for when things go wrong. This is the same kind of product. Once you have that in place, remember, it’s not a fail-safe; it’s not a defensive system. That’s why I say it’s the third and final resort. But it offers two things. It offers bottom-line protection: Let’s say you have $10 million worth of coverage, and then the bad thing happens. You know that you can be restored up to the $10 million that hit your bottom line.

The other thing that cyber insurance often entails is breach response services. So they can help you build out a program to protect yourself when something happens. They can provide you with vendors, they can provide you with legal counsel, they can provide you with public relations experts, and so they can help build that suite of services around you and your business that are needed to deal with an incident.

Now, most businesses have their own cybersecurity plans and their own incident response plans. One of the biggest flaws that I see in incident response planning is that a company will have its own incident response plan, and then it will also have these cyber insurance resources, but they won’t be integrated. And so the problem there is if you use your own people, and you don’t get consent to use them, the insurance company might say, Hey, we’re not paying for that. So the best thing that you can do is work to get insurance involved on the front end working to make sure the insurance company signed off on the plan so that seamlessly integrates. So when something bad happens, you can bring all those resources to bear.

**ME: Should health care organizations ever pay the ransom?**

**Halprin:** This is probably one of the trickiest moral and ethical dilemmas for businesses. As a lawyer, I can’t advise anyone to break the law. And if you speak to law enforcement, the overwhelming suggestion is don’t pay. The reason they don’t want you to pay is they don’t want the criminals to be incentivized to continue doing what they’re doing. There are also sometimes actors that are on the sanctions list, right? They’re people that we as a country do not permit our citizens to engage with. So there are a lot of considerations as to why it’s not a good idea to pay.

One other consideration about not paying is sometimes you pay and the actor stays in your system and continues to extort. So you’re not even promised that you’ll get free and clear access from paying. And then even the worst part is, you could get free and clear access, but everything’s corrupted now that they’ve left. And so you get very little for what you pay. Those are all the reasons not to.

But what I think businesses often do practically, especially those in the health care space, is they just pay. I can’t give you a number or a statistic. But overwhelmingly when clients are hiring me and they’re fighting with their insurer; oftentimes it’s because they want to get the insurer to cover the ransom. And I would say if you have a cyber policy that covers ransomware, insurers are amenable to you making those payments and to reimbursing those payments.

**ME:** Something we often hear from physicians at small or solo practices is they don’t believe they are really being targeted. How true is that?

**Halprin:** It’s not true at all. It’s more kind of a shotgun and goes in a lot of different directions. I don’t think (hackers) are necessarily saying, I want to hit small practices in the Midwest, but it may necessarily end up being that way. There are targeted attacks, for sure, which do end up hitting the larger organizations, but I think that for the smaller medical practices, it’s not necessarily because they picked you. It was more that you happen to have a vulnerability that’s not patched.

**ME:** Is there anything else that’s important for physicians to know about the subject that we haven’t discussed?

**Halprin:** Just to take this seriously. Some of the questions that physicians have: If I’m going to get hit with this anyway, what’s the point? Why bother? I think the answer is you still want to be prepared. And you still want to take precautions. Because if you’re too nonchalant about it, it could end your business.
Don’t let administrative burdens wreck your practice

by Jeffrey Bendix Senior Editor

“I wish I could do more paperwork,” said no doctor, ever.

Tasks such as filling out forms, checking boxes and fighting with insurance companies have long irritated physicians. But several trends have converged in recent years to bring what had been simmering discontent over administrative and regulatory burden to a boil. Chief among these are the spread of electronic health records (EHRs) and their accompanying documentation requirements, and the growing number of procedures and medications requiring prior authorizations.

Then, in 2020, the brew of physician frustration grew even more toxic with the arrival of COVID-19. Suddenly, doctors found themselves confronted with a whole new array of health and safety mandates, along with needing to reconfigure their practices to care for patients remotely rather than in person.
The impact of paperwork, regulatory burden
Given these developments, it’s hardly surprising that “too much paperwork and regulations” was the leading cause of burnout cited in the 2021 Medical Economics® Physician Burnout and Wellness Survey. Similarly, 91% of those surveyed by the Medical Group Management Association (MGMA) for its 2021 regulatory burden report said their overall regulatory burden had increased during the previous year — up from 86% in 2018 and 2019.

But even if some administrative tasks are unavoidable in fee-for-service medicine, practice consultants and management experts say there is still much doctors can do to reduce their share of the paperwork load and free up more time for seeing patients.

Tackling the EHR
One of the biggest sources of paperwork and administrative tasks is the EHR. Numerous studies have documented EHRs’ impact on the amount of time doctors spend with patients and their overall workloads. For example, a 2016 study of 57 doctors’ daily activities published in Annals of Internal Medicine found that physicians spent 49% of their total time on EHR and desk work and only 27% on direct clinical face time with patients.

“The EHR has been and continues to be a huge source of added time and frustration for physicians,” says Adrienne Lloyd, MHA, FACHE, founder and CEO of consulting firm Optimize Healthcare and a former MGMA practice consultant. “Most of them understand the need for it from a medical perspective but it’s not a value added from the patient perspective.”

EHRs actually pose three separate, interconnected challenges for physicians in outpatient practices, according to Ron Holder, M.H.A., MGMA’s chief operating officer. First is their lack of user-friendliness, a flaw arising from the fact that they weren’t originally designed for medical purposes.

“Many EHRs are really billing systems disguised as a medical record,” Holder explains. “So if the technology is designed for simplification of the billing process, that rarely translates into ease of use when working with it clinically.” And while vendors have made some progress in correcting this, many users still find them difficult to navigate and counterintuitive and resent the additional hours of charting they create.

The second problem, says Holder, arises from the frequent mismatch between the needs of outpatient primary care practices and their parent hospital system. “If you’re part of an integrated delivery system it’s likely that the people making the purchasing decisions are buying an EHR that looks good for a hospital, but that often doesn’t translate into being user friendly for an outpatient practice,” he says. “When you take a product that was designed to do X and try and make it do Y it’s going to cause a lot of frustration.”

Finally, when selecting an EHR system many practices don’t consider how it’s going to affect their workflow. “They mistakenly think they can beat the EHR round hole into the square peg of how they’ve always practiced,” Holder says. Ultimately, he adds, most practices find it’s better to tailor their workflows to fit the EHR rather than the other way around.

“You have to be willing to use the tool how it’s supposed to be used,” Holder adds. “It stinks at the beginning, but it gets much easier later on.”

The value of scribes
So what can primary care doctors, and the practices that employ them, do to ease some of the administrative burdens caused by EHRs? A good place to start, and one that’s been growing in popularity, is to use scribes to document patient visits. In a 2018 JAMA Internal Medicine study, 69% of PCPs using scribes reported spending an hour per day less on EHR documentation compared with those not using scribes, 94% reported greater job satisfaction and 89% reported improved clinical
interaction with scribes present.

While some practices balk at the cost of hiring scribes, in many cases they pay for themselves through time savings and added efficiency, notes Owen Dahl, MBA, CHBC, principal of Owen Dahl Consulting. “If I can get, say, $70 for a (CPT code) 99213 established patient office visit, and a scribe allows me to see two more patients per day, then I’ve paid for that scribe,” he notes.

“When you take a product that was designed to do X and try and make it do Y it’s going to cause a lot of frustration.”

Customize the software
Another technique for improving EHR efficiency, according to Lloyd, is to build order sets and templates. The former consist of services the doctor routinely orders for patients when they reach a certain age or have a chronic condition.

“The EHR generates everything that’s needed (for those services) so the doctor doesn’t have to hunt for each one separately, which makes the process a lot easier for them,” she says.

In a related way, templates enable physicians to standardize and customize their notes, with different fields for vital signs and other things the doctor might want to check, again depending on the patient’s age, gender and chronic conditions. The EHR can then be programmed to use that information as the basis for a note. “So there are ways of building in some automation so the doctor doesn’t have to repeat the same step for each patient,” Lloyd explains.

Sometimes the biggest obstacle to implementing such shortcuts is the doctors themselves, Lloyd says. “It’s getting them to take the time to step back and look at what they do most often so you can build those templates and order sets for them. And it doesn’t take a ton of time; it’s just getting the providers to believe it will help them and getting someone to execute on those things from an IT perspective.”

The technical skills needed for configuring the EHR may require an outside consultant but sometimes a tech-savvy person already on staff is enough. “Even in a small practice often there’s at least one person who can help with configuring the system back and look at what they do most often you can build those tem-

Reducing the prior authorization burden
The time demands of prior authorizations are another source of frustration for many doctors. In MGMA’s regulatory burden report, 88% of respondents called prior authorization requirements “very” or “extremely” burdensome, up from 82% who used those terms in 2018.

But while prior auths may not be avoidable, experts say there are ways to minimize the burden they impose. One of the most effective, says Dahl, is to compile a running list of which procedures and prescription medications require prior auths from which payers, and under what circumstances. Such information usually can be obtained from the payer’s website and by calling them.

Sometimes, he adds, a payer’s prior authorization requirements will vary even from patient to patient, so it’s important to include the practice’s own prior auth requests and their outcomes. “Don’t just say, ‘We got the authorization’ and leave it at that,” Dahl advises. “Audit what happens with the denials and the authorization hassles encountered. Be aware of the documented requirements and ask, ‘Are we providing that documentation and doing so in a timely manner?’”

Analyzing this information usually will clarify which procedures routinely need prior auths from which payers and therefore can be obtained without the doctor getting involved. “I suspect most practices would find the doctor is only needed in about 20% of requests,” he says.

But this process doesn’t relieve doctors of all prior auth responsibilities, Dahl adds. “There’s still some burden on the doctor to make sure what they’re ordering is adequately documented and that there’s sufficient information for the staff to take on the responsibility of communicating with the payer,” he says.

Holder says thorough documentation provides useful ammunition
for the times when, even after submitting it, the payer requires a physician-to-physician phone call before it will authorize coverage. “That allows you to say to them, ‘The information is all there in my note. Why am I having to call about this?’” he says.

**Negotiating prior auths with payers**

Holder adds that prior authorizations can become part of payer contract negotiations by, for example, specifying the circumstances under which the doctor does and does not have to get involved in the process. “You can make the argument (to the payer) that they’re limiting your ability to care for their patients by having to spend time on the phone with them,” he points out.

In addition to EHRs and prior auths, experts say doctors can reduce their non-clinical workload by delegating tasks that don’t require the doctor’s input — and ensuring staff members are trained to do them. Lloyd cites the example of assigning a staffer to take patients’ medical histories before they see the doctor.

“The staffer will need to know what information the doctor wants to have before walking in the room with that patient,” she says. “It’s all about allowing the provider to focus on the areas where they can have maximum impact.”

The ability to delegate effectively also requires strong bonds between doctors and staff, says Holder. “Then people are acting out of loyalty. They know you’re working to make them successful and happy and when that happens the team wants to take as much off the physician’s plate as they can.”

***Is AI the solution to documentation woes?***

Since computers—in the form of electronic health records—have caused so much of the paperwork burdening primary care doctors nowadays, could they also provide a way to reduce that burden? A project underway at the American Academy of Family Physicians (AAFP) suggests that they could.

AAFP has partnered with Suki, a manufacturer of software that integrates voice recognition and artificial intelligence, to develop AI Assistant for Documentation, a program that combines machine learning — a technology that mimics the human brain’s neural network — and voice recognition software to generate documentation of patient visits.

In December 2021, the AAFP announced results of the second phase of a study of the program’s effectiveness. It found that primary care practices using the program saw a 72% reduction in the median documentation time per note, resulting in a time savings of 3.3 hours per week per clinician. Participants also reported improved levels of job satisfaction and decreased feelings of burnout.

Steve Waldren, M.D., M.S., vice president and chief medical informatics officer for AAFP, said AI Assistant differs from standard voice recognition software in its greater ability to understand voice commands. “You can tell it things like, ‘Suki, change my abdominal exam note to ‘mildly distended,’ and it understands that it needs to go to the physical exam, then the abdomen section, and replace the text that’s there with what you just said.”

Waldren noted the program also can be synced with smartphones and other mobile devices, allowing users to dictate notes whenever and wherever they choose. “The nice thing about leveraging smartphones is that they’ve been designed to enable voice because of features like Siri and Google Assistant, which also means docs don’t have to purchase additional hardware to attain that flexibility.”

The program is available for purchase starting at $199, Waldren said.
A physician’s goal is to care for patients, but a key part of being able to provide that care is the eternal quest for payment. One way to ensure that a practice maximizes its coding regimen is to make sure each session can be efficiently billed. Adhering to the following expert coding tips can help practices supercharge their revenue.

Don’t tinker around the margins
Bill Dacey, M.H.A./MBA, president and CEO of The Dacey Group in Palm Harbor, Florida, says that when some people consider supercharging their coding practices, they think of including smaller things for which they are not already billing. He warns that this approach may not be as effective as expected.

“My approach to this has always been to stop working the corners and the little $3 codes and counting all that little stuff,” he says. “Why don’t you just make sure you’re doing the stuff that you do 99% of the time? That will probably get your revenue where it’s supposed to be.”

Dacey says mastering the new outpatient coding guidelines, released last year, can help shore up revenues by enabling practices to bill for what the new guidance allows. He gives the example of code 99213 for an evaluation and management visit.

“It’s the most commonly reported code in the country, and it’s been a 99213 for 30-odd years, but with the changes that came in 2021, it makes it a whole lot easier to call that a 99214,” he says. Dacey says this feels off to longtime physicians because it has been an evaluation and management level three for so long, but now it is a level four.

“If (a practice) wanted to supercharge their coding, I would do it with the codes that had the real money,” Dacey says. “You’re doing the exact same thing you did two years ago, but now it’s worth 50% more.”

This change can be uncomfortable to implement, but Dacey says it is lucrative. “There (are) only five established patient codes … and the 99213, which has been the workhorse code forever, has now kind of slipped down a notch,” he explains. “Family medicine alone did $2 billion in 99213 last year and internal medicine another $3 billion. And that’s where the money is … most all of the money.”

Documentation is key
Nancy Enos, FACMPE, CPC-I, coding consultant with Enos Medical Coding in Warwick, Rhode Island, says the key to getting the most revenue through coding is proper documentation of time spent. “It’s all about the documentation,” she says.

A focus on extensive documentation allows practices to keep track of all time spent on a patient session, enabling efficient billing. She recommends that physicians receive brief internal or external training on documentation.

“(This) will pay off in spades, because if they write certain elements, certain parts of their
note, they will translate to the higher codes,” she says. Enos says this documentation becomes very important when billing for nonpatient-facing activities.

**Nonpatient-facing activities**

Enos also recommends that practices understand which nonpatient-facing activities still count for time. “There are several different things that count as reportable time as long as they’re performed by a billing provider on the same date as the billable visit,” she says. “It can’t be the day before, it can’t be the medical assistant — it has to be a billing provider and it has to be the same date.”

“There are so many things that they can just confirm, like the patient history and labs that were collected by their support staff,” she says. “Then when they review it on the day of the service before they see the patient, that could be another 20 minutes that is billable time toward the level of service, as well as after the patient leaves — any calls to physicians to put in place any coordination of care, (and) documenting and updating the medical record itself is now billable time that never was counted before 2021.”

Enos also recommends ensuring a practice keeps track of time when it comes to telehealth appointments. “There are instances where a telemedicine visit results in advice to come into the office because the patient does need to be seen,” she says. “You can only bill one visit per patient per day, so it’s just the office visit. The telemedicine visit is separately billed, but you can bill for total time spent on the day of the encounter. If you’re coding based on time, then you could add the time together for the telemedicine visit and the in-office visit.”

She notes that this is also a good reason to get your practice’s documentation in order, because properly documented activities are more likely to withstand scrutiny from insurance companies. Enos says that over the past year of audits she had seen some bullet statements listing only the total time spent on one or more of a list of the activities that count without a specific time accounting of time spent on each task. “I would not want insurance companies to audit that I may have done one of the following,” she says. “That doesn’t seem very provable.”
Another episode of overt hepatic encephalopathy (OHE) may be right around the corner. What can you do to reduce your patient’s risk of recurrence?

"I was oblivious to what was going on around me"

Align with the guidelines for patients at risk

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.

INDICATION

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.

XIFAXAN is the only FDA-approved agent indicated for the reduction in risk of OHE recurrence in adults.²

In a clinical trial of adults, XIFAXAN cut the risk of OHE recurrence and HE-related hospitalizations in half²

91% of patients in the placebo and XIFAXAN groups were on lactulose²

Study design²:³
- In a randomized, placebo-controlled, double-blind, multicenter, multinational, 6-month study, the efficacy of XIFAXAN 550 mg (taken orally twice a day) was evaluated in 299 adult subjects
- Inclusion criteria: Currently in remission (Conn score of 0 or 1) from HE and ≥2 episodes of HE associated with chronic liver disease in the previous 6 months
- Primary endpoint: Time to first breakthrough overt HE episode, defined as a marked deterioration in neurological function (an increase in Conn score to grade ≥2 or an increase in Conn score and asterisks grade of 1 each if subject entered study at grade 0)
- Key secondary endpoint: HE-related hospitalization

IMPORTANT SAFETY INFORMATION (continued)

- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (P-gp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In a clinical study, the most common adverse reactions for XIFAXAN in HE (≥10%) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required.
- XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see brief summary of full Prescribing Information on the following pages.
1.2 Hepatic Encephalopathy
XIFAXAN is indicated for reduction in risk of overt hepatic encephalopathy in adults.

4. CONTRAINDICATIONS
XIFAXAN is contraindicated in patients with a hypersensitivity reaction to rifaximin or any of the components in XIFAXAN. Hypersensitivity reactions have included anaphylaxis and angioedema, and anaphylaxis. [See Adverse Reactions (6.2)].

5. WARNINGS AND PRECAUTIONS
5.2 Clostridium difficile-Associated Diarrhea
Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterials, including XIFAXAN. CDAD ranged in severity from mild diarrhea to fatal colitis. Treatment with antibacterials alters the normal flora of the colon which may lead to overgrowth of C. difficile. C. difficile toxin causes intestinal inflammation and diarrhea. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

5.4 Severe (Child-Pugh Class C) Hepatic Impairment
There is limited systemic exposure in patients with severe hepatic impairment. The clinical trials were limited to patients with Child-Pugh C. Therefore, caution should be exercised when administering XIFAXAN to patients with severe hepatic impairment (Child-Pugh Class C). [See Use in Specific Populations (8.7), Clinical Studies (14.2)].

5.5 Concomitant Use with P-glycoprotein Inhibitors
Concomitant administration of drugs that are P-glycoprotein (P-gp) inhibitors with XIFAXAN can substantially increase the systemic exposure to rifaximin. Concomitant administration of rifaximin with P-gp inhibitors may further increase the systemic exposure to rifaximin. Caution should be exercised when concomitant use of XIFAXAN and a P-gp inhibitor such as cyclosporine is needed. [See Warnings and Precautions (5.5), Clinical Pharmacology (12.3)].

7.2 Warfarin
Changes in INR have been reported postmarketing in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be needed to maintain target INR range. See prescribing information for warfarin.

7.3 CYP3A4 Substrates
An in vitro study has shown that rifaximin induces CYP3A4. [See Clinical Pharmacology (12.3)]. However, in patients with normal liver function, the rifaximin recommended dosing regimen is not expected to induce CYP3A4. It is unknown whether rifaximin can have a significant effect on the pharmacokinetics of concomitant CYP3A4 substrates that are associated with reduced liver function who have elevated rifaximin concentrations.

8. USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no available data on XIFAXAN use in pregnant women to inform drug-associated risks. Teratogenic effects were observed in animal reproduction studies following administration of rifaximin to pregnant rats and rabbits during organogenesis at doses approximately 0.9 to 7.3 times and 0.3 to 3.3 times, respectively, of the recommended human doses of 600 mg to 1650 mg per day. In rabbits, oral, ocular and maxillofacial, cardiac, and lumbar spine malformations were observed. Oral malformations were observed in both rats and rabbits at doses that caused reduced maternal weight gain (see Data). 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. Advise pregnant women of the potential risk to the fetus. Data

8.5 Geriatric Use
The safety and effectiveness of XIFAXAN has not been established in pediatric patients less than 18 years of age for HE.

8.6 Renal Impairment
The pharmacokinetics of rifaximin in patients with impaired renal function has not been studied.

9.7 Hepatic Impairment
Following administration of XIFAXAN 550 mg twice daily to patients with a history of hepatic encephalopathy, the systemic exposure (AUC) of rifaximin was about 10-, 14-, and 21-fold higher than in those patients with mild (Child-Pugh Class A), moderate (Child-Pugh B) and severe (Child-Pugh Class C) hepatic impairment, respectively, compared to that in healthy volunteers. No dosage adjustment is recommended for rifaximin in patients with severe hepatic impairment. [See Warnings and Precautions (5.4), Clinical Pharmacology (12.3), Clinical Studies (14.2)].

10. OVERDOSAGE
No specific information is available on the treatment of overdosage with XIFAXAN. In clinical studies at doses higher than the recommended dose (greater than 1,100 mg per day for HE), adverse reactions were similar in subjects who received doses higher than the recommended dose and placebo. In the case of overdose, discontinue XIFAXAN, treat symptomatically, and institute supportive measures as required.

13. NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Maternal soft tissues in the heart were significantly increased in male Crl:CD (SD) rats that received rifaximin by oral gavage for two years at 150 to 250 mg/kg per day (doses equivalent to 1.3 to 2.2 times the recommended dose of 550 mg twice daily for HE, based on relative body surface area comparisons). There was no increase in tumors in Tg(Nash 2) mice dosed orally with rifaximin for 26 weeks at 150 to 2000 mg/kg per day (doses equivalent to 4.7 to 67 times the recommended daily dose for HE, based on relative body surface area comparisons).

13.2 Carcinogenesis

13.3 Mutagenesis

13.4 Impairment of Fertility
Elevated in male Crl:CD (SD) rats that received rifaximin at doses of 0.7 to 11 times the recommended dose (greater than 1,100 mg per day for HE), adverse reactions were similar in subjects who received doses higher than the recommended dose and placebo. In the case of overdose, discontinue XIFAXAN, treat symptomatically, and institute supportive measures as required.

Rifaximin for Travelers’ Diarrhea, Hepatic encephalopathy and IBS are protected by U.S. Patent Nos. 7,045,620; 7,612,199; 7,984,232; 7,962,206; 7,998,542; 8,188,781; 8,158,644; 8,193,196; 8,518,949; 8,745,904; 8,835,452; 8,853,231; 9,060,398; 9,271,968; and U.S. Patent Nos. 6,862,573; 8,289,017; 8,946,252; 8,969,368; 9,421,195; 9,029,926; 10,314,828; 10,335,397; and 10,706,532. Rifaximin for IBS is also protected by U.S. Patent Nos. 6,786,053; 7,452,857; 7,605,240; 7,718,608; 7,915,275; 8,015,846; 8,196,567; 8,355,800; 8,390,059; and 8,741,904.
For 15 years, I unquestioningly followed my organization’s standard process for patient flow. After all, I had been “flow mapped” and “cycle time measured” by a team of managers with Toyota-lean precision, so I assumed this must be the most efficient way to run a practice.

You know the routine I’m talking about. The patient arrives at the check-in window to register and sits down to wait. A medical assistant (MA) shows up holding a chart, calls the patient’s name, and walks them into the clinical area. First stop: the dreaded scale for a weight. Next, into the exam room for vital signs: blood pressure, pulse and temperature. Now, the MA barrages the patient with questions, typing furiously into an electronic system for the next five to 10 minutes or more, depending on the historian. Many of these questions will turn out to be completely irrelevant, already in the chart, or repeated by the physician. Finally, the MA leaves the patient alone in the exam room to wait — and sometimes wait, and wait — until the doctor finally rushes in.

Ah! This is the big moment, and in my opinion, where the magic happens. Doctor and patient sit together and have what seems to be the casual observer to be a simple conversation. As the patient talks about their concerns, the doctor probes deeper, asking the relevant questions that have been honed by years of practice in history-taking. During this interview process, the physician will use open-ended questions, work to establish patient trust and apply advanced techniques like motivational interviewing to help guide the patient toward optimal health. The physician not only asks about physical complaints but also addresses wellness issues such as ensuring that appropriate screening tests have been ordered. After a medical plan has been determined, the physician leaves the exam room to rush to the next patient, leaving the MA to complete orders and accompany the patient to the checkout area.

If this orchestrated ballet works perfectly, the patient is out of the office in about an hour, perhaps 15 minutes of which was spent with the physician. Administrators and workflow experts assure doctors that this type of streamlining leads to the most efficient visit and “patient experience.” After all, it takes a team to care for patients these days! Or does it?

Flipping the script
Imagine a different scenario. The patient arrives at the office, checks in, and takes a seat. Their own doctor arrives at the door of the waiting room, recognizes their long-term patient by sight, smiles and beckons them into the office. Wait, what?

Stay with me.

The doctor then walks the patient down the hall into the exam room, making small talk and building rapport. Both enter the exam room, take a seat, and continue to chat for a few moments. The patient has gotten over their surprise at seeing the doctor so quickly and is now relaxed and comfortable, entering into the history portion of the visit without the usual irritation or even anger at waiting or repeating answers to the same questions over and over. Empathy and trust now sufficiently established, the doctor opens the patient’s chart, and moves right into obtaining the patient’s history.

“Patients are not machines and medical offices are not manufacturing plants.”
Now I’m about to get even more radical on you. Imagine that, once the history has been taken, the doctor obtains their own vital signs. It’s shocking, I know, and counterintuitive to everything the Toyota people have told us about delegation of duties. But doesn’t it make so much more sense?

First, the patient has been sitting for about 10 minutes, ensuring a more accurate blood pressure reading than one taken immediately after the patient walks into the office. It also helps patients avoid anxiety and stigma over being weighed. While obtaining weight as a health examination is critical, we know that the scale can be emotionally distressing to some patients. Explaining to a scale-averse patient the rationale for obtaining their weight or allowing them to stand on the scale backwards to avoid seeing the number (a technique some patients with eating disorders employ) may improve their willingness. In many cases, patients who entered the office fearing being weighed will jump on the scale when they realize that their doctor is supportive.

Second, obtaining vitals after the history is consistent with the way physicians are trained to think. In a “SOAP” (subjective, objective, assessment, plan) note format, the physical exam supplements the history in medical decision-making, unless, of course, the patient appears immediately unstable when they walk in the door. It allows the doctor to decide whether additional vital signs like temperature or pulse oximetry are indicated, perhaps not if the patient is presenting to follow up on depression, or example. Most importantly, taking your own vitals ensures that the physician does not miss abnormal readings that are easy to gloss over when looking at a piece of paper or a computer screen. We know that vital signs truly are “vital,” and yet I cannot be the only doctor to admit that I have found myself distracted by a patient’s multiple concerns and noticed an abnormal vital sign reading only as I was doing my notes later in the day, necessitating an urgent recall of the patient.

**Hands-on care**

Probably the most important aspect of taking your own vitals is that it allows the physician to have a truly hands-on experience with the patient. In a traditional busy office setting, patients may feel rushed and that “the doctor never even touched me.” Sometimes there is a good reason for that; maybe the doctor didn’t have the chance to examine them because so much time was spent in discussion, or because an exam wasn’t medically necessary for that particular complaint. Perhaps the doctor did do an abbreviated exam while talking to the patient, but the patient was too distracted to even realize it. Taking your own vital signs allows the patient to truly feel a physical connection with their physician, even if it was only the minute or two that you took to apply a blood pressure cuff.

Another way to achieve a truly hands-on experience is to consider performing your own phlebotomy. Although many physicians haven’t drawn blood since medical school or residency days, consider that phlebotomy is far less invasive than many other procedures we do for our patients, and skills can be quickly refreshed after a few hours watching and practicing with an experienced phlebotomist (most labs are happy to offer this service). Drawing blood is also a satisfying way to wrap up your patient visit, drawing the visit to a natural conclusion.

Physicians may also find that they enjoy other clinical tasks usually relegated to assistants, like administering immunizations or performing EKGs, or may choose to bring in an assistant to complete those tasks. After the clinical work is complete, the final step is to perform clerical duties like scheduling tests, procedures, and referrals; tracking down medical records and setting up a follow-up visit, which can be assigned to a nonclinical assistant.

**Results of this approach**

I know that the idea of doing more hands-on clinical duties as a physician completely contradicts the past 20 years of practice management advice, which has urged us to practice assembly line medicine to “see more patients.” But patients are not machines and medical offices are not manufacturing plants. In fact, patients report the most satisfaction with their office visit when the time they spend with the physician “meets or exceeds their expectations” and get better outcomes when they feel a true connection with their doctor based on trust and mutual understanding. By cutting out intermediaries, patients get exactly what they want and need: time with their doctor.

Physicians also benefit from this strategy. Happier patients are more adherent to medical regimens, show improved disease self-management skills and are less likely to sue for malpractice. Having fewer staff members may reduce the risk of data entry errors and increase team accountability. Believe it or not, taking your own history and vital signs may save you time, as one of the biggest bottlenecks in a practice is time it takes to “room” patients.

But can this strategy actually save a practice money? It depends. If the physician’s labor must subsidize a C-suite of managers — the kind that pay hefty consulting fees to those office flow “experts” — probably not. But for a small practice where support staff salaries and benefits make up the largest portion of overhead, a reduction in staff members may balance a decrease in total number of office visits per day. Adding a scribe to take notes during each visit can allow a physician to see more patients.

While implementing all these measures may not be possible in your office, consider what small changes you could make to allow you to spend more time with your patients.

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How to invest in real estate (without being a landlord)

by Jordan Rosenfeld

Physicians with an interest in adding real estate investments to their portfolio may wonder how they can possibly make the time to manage properties and do their jobs. But real estate experts offer several ways to earn passive or semi-passive income from real estate that don’t require becoming a landlord in the traditional sense. For physicians, who tend to be high earners, real estate investments can also have tax breaks.

Figure out your goals
To figure out the right real estate investment strategy, it’s useful to first outline your financial goals, according to Harry Nima Zegarra, MD, a pulmonary and critical care physician at Baylor University Medical Center in Dallas, Texas, and owner of Nima Equity. “A return on investment is important, but as important is how much time do you want to devote to doing certain types of activities?” he asked.

Real estate has multiple advantages, he said, including “cash flow, appreciation, leverage, the equity that keeps building when paying your mortgage, and tax benefits.”

Nima Zegarra, who has an active real estate portfolio, first became excited about real estate’s wealth building possibilities after selling a home he and his wife had bought in 2011 that had appreciated significantly in the years they owned it. They did not want to spend the time and effort that goes into property management and soon found out about real estate syndication.

Real estate syndication
Real estate syndication is where a group of investors come together to purchase a property at a price that none of them could afford individually. After the property appreciates over time, they sell it and share the profits, according to Eli Goodman, a licensed real estate agent with Illinois Real Estate Buyers in Chicago, Illinois.

In this method, a $2 million to $3 million investment is raised by the investor group, which can include any individuals who decide to invest together, Goodman said. Once the capital is raised, the real estate syndicator oversees all the hard work. “The promoter of this would find the assets, raise the capital, buy the property, raise the value, stabilize it, and manage it,” Goodman said.

Nima Zegarra and his investment group prefer to purchase apartment complexes. So not only do the investors receive passive rental cash flow during the year, which he estimates at a 7% to 10% return each year, but they also gain appreciation as the building increases in value. In four to six years,
Taking advantage of increased value in equity and repairs?

It’s also possible to pay a broker to do the flipping process, according to Brian LeBow, a licensed real estate broker and owner of Bell Properties in Arcadia, California. “You can rinse and repeat. You don’t have to keep your money tied up in a property forever,” he said.

“A return on investment is important, but as important is how much time do you want to devote to doing certain types of activities?”

Work with a property manager

While becoming a landlord may not appeal, cash flow from rental properties can be a great form of passive income, LeBow said. But physicians don’t have to manage the properties themselves; they can outsource that work to a property management company. In LeBow’s experience, “A lot of clients will go six or seven months without any communication with their property managers. Many physicians will give property managers a financial authorization to take care of any repairs or issues that crop up. “It can be really hands off for them,” he said. “We have one doctor with a 30-unit apartment complex in Glendale, California. We talk to him maybe once a year around tax time.”

There are property management software programs that simplify and automate the daily tasks of being a landlord, according to Chris Lee, owner of Landlord Gurus, a website that offers advice to independent landlords and rental owners.

“Property management software simplifies and automates the daily responsibilities of landlords, from advertising, tenant screening, bookkeeping and rent collection.” Tenants can even pay their rent directly through the software’s portal.

Lend money to other real estate buyers

Perhaps the most passive form of return in the realm of real estate is to simply lend money to those who need loans to buy properties, McGriff said. Not only do you get a good return on your money, but in the worst-case scenario, when someone defaults on the property, you acquire it. “You can be extremely passive.”

Goodman says an investor can make as much as an 18% return annually on lending money.

Buy your own building

Physicians who have the opportunity to buy the building they work in can take advantage of generous tax benefits, LeBow said. “You can write off big chunks of depreciation over time,” he pointed out, as well as management fees and other costs related to the upkeep of the building.

However a physician begins to build a real estate portfolio, Nima Zegarra urged, “The first thing I would do is get educated. Do some research, start reading, network. You should do your due diligence before investing a good amount of your hard-earned money.”

Buy low, renovate and flip

Another real estate method that doesn’t require becoming a landlord is to, essentially, “flip” houses by buying at a low price then investing in renovations and selling it at a higher purchase price, McGriff said. “There are a lot of opportunities in California and nationwide for physicians to buy low and do renovations. California in particular has sub-markets where there’s an opportunity to get into assets that have not been serviced or maintained.”

While this method is still passive over time, it requires a lot more work up front, and a physician should ask some important questions, McGriff said. “Do they want to hold it for a duration, or do they want to renovate and then sell the assets and take advantage of increased value in equity and repairs?”

The benefit is that it’s a passive form of income building once one has done the legwork to find the right syndication group, which, Nima Zegarra says, takes time and research. And returns can be quite good, as much as 10% to 15% return annually, according to rental investor and broker Donnie McGriff, owner of Echo Properties in Dothan, Alabama.

Nima Zegarra said his group aims for 50% to 60% percent gains on the amount of investment, selling at year 5.

Many physicians will give property

While the returns on syndication can be very good, Nima Zegarra warns that this is not a liquid investment. “If I change my mind in two months in stocks, I can sell my stocks and get my money. In syndication it’s usually an investment for four to six years,” he explained.

Additionally, most of these types of investing require a significant upfront layout, from $50,000 to considerably more. And every investor has to pay the syndicator an entrance fee and an exit fee, typically in the form of a percentage on the return.

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the syndicate sells the building and splits the equity.

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3 options for short-term medical practice loans

Sometimes a long-term loan, such as from a bank or an SBA 7(a) Guaranteed Loan, simply does not make sense for a small medical practice. With term lengths typically shorter than five years, short-term loans are ideal for meeting the immediate needs of a medical practice, such as upgrading office equipment, restocking inventory, covering delayed bill payments or increasing cash flow without spending restrictions. There are three common short-term funding options for doctors and medical professionals:

- Merchant cash advances
- Lines of credit
- Invoice factoring

**Merchant cash advances**

A merchant cash advance (MCA) is not actually a loan. Offered by alternative online lenders, an MCA is technically a form of financing known as an asset purchase. In exchange for a cash advance, your lender will automatically deduct a portion of your practice’s future earnings until the advance is repaid.

Payment amounts are based on your revenue, which means when revenue is lower, your payments will be reduced — and vice versa. As opposed to traditional interest rates, MCAs use what is known as a factor rate based on the financial history of your business. The stronger your history, the lower your rate should be.

It is often easier to get an MCA than other forms of funding because approval requirements tend to be less strict than those for traditional medical practice loans. MCAs also typically do not require collateral. However, MCA regulations vary by state and not all providers are reputable, so do research before signing a contract.

**Business lines of credit**

A line of credit gives you access to working capital without the obligations of a fixed-term loan. Lines of credit give you the flexibility to withdraw as much or as little as you need provided you do not exceed the credit limit, and if your business is performing as well or better than when the line of credit was approved. You can withdraw and repay as many times as needed, and only pay interest on the portion of money borrowed against the line of credit.

Business lines of credit are available from traditional and alternative lenders. Traditional lenders typically have stricter approval requirements such as high minimum credit scores, whereas alternative lenders are more flexible and will consider other factors. When you apply for a business line of credit from an alternative lender, your approval will be based on the revenue and cash flow of your medical practice as well as these factors:

- Vendor payment history.
- Years in business.
- Industry type.
- Public records.
- Personal credit.

**Lines of credit are best for medical practices:**

- With a strong credit history that want a cushion to fill cash flow shortages
- That need flexible access to working capital

**Invoice factoring**

Also known as accounts receivable financing, invoice factoring allows doctors to sell their outstanding invoices to a lender in exchange for the net amount in cash. Typically, the lender will advance the medical practice 70% to 90% of the invoice’s value, often up to a maximum of $100,000 per common ownership. Once your client pays their bill, the lender will remit the remaining 10% to 30% of the invoice — minus the lending fee.

Invoice factoring offers shorter repayment terms than other short-term financing options, typically aligning with your accounts receivable period — generally between 60 and 120 days. There is no standard factoring agreement, so be prepared to negotiate the terms.

When you apply, your lender (called a “factor”) will:

- Review and determine your client’s (or client base’s) creditworthiness.
- Review previous invoices and assess how successful you have been in collecting payment.
- Negotiate with you based on the results of their risk assessment.

When you choose invoice factoring, the factor oversees collecting payment from your clients. That is why it is important to choose a lender you can trust to treat your clients tactfully during the collection process. The last thing you want to do is compromise your business relationship with your clients.

**Invoice factoring is best for medical practices:**

- With long accounts receivable periods.
- That need to fill in the gaps between sending invoices and receiving payment.
- With invoices valued over $15,000 with extended credit terms, and that are not more than 90 days past due.

Alfredo Rosing is vice president of marketing at Greenbox Capital. Send your financial questions to medec@mjhllifesciences.com.
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Welcome to this Medical Economics® presentation of “Around the Practice,” featuring a panel discussion on the current state of the opioid epidemic in the United States and the role of naloxone for the emergency treatment of patients with a known or suspected overdose.

Let’s meet our panel members:

Moderator:
Matthew Torrington, M.D.
Family medicine physician with a specialty in addiction medicine and a background in clinical research and drug development who practices in Culver City, California

Panelists:
Daniel E. Buffington, Pharm.D., MBA
President and CEO at Clinical Pharmacology Services, Inc, in Tampa, Florida

Thomas Kosten, MD
Jay H. Waggoner Endowed Chair and professor of psychiatry, pharmacology, immunology and neuroscience; vice chair for psychiatry; and co-director of the Dan L. Duncan Institute for Clinical and Translational Research at Baylor College of Medicine, Houston, Texas

Bill H. McCarberg, MD
Founder of the chronic pain management program for Kaiser Permanente and adjunct assistant clinical professor at the University of California San Diego School of Medicine, San Diego, California

The interactive panel discussion was filmed and the following transcript was edited for length and clarity. To view the full video discussion, including panel discussions of 2 unique patient scenarios, visit:

Opioid abuse and the role of naloxone

Torrington: How would you characterize the overall trajectory of the opioid overdose epidemic and where we stand at this point?

Kosten: First, this is not a new epidemic. Its onset was around 2015, or at least 2017, and while it began with overprescribing of opiates, fentanyl has taken over. Fentanyl is manufactured in China and Mexico and imported to the United States. In the illicit drug market, fentanyl is now being disguised, that is, it is being mixed in with heroin, methamphetamine, and cocaine – it’s all white powder. On the internet it is sold as pills that look like Percocet or Adderall or Valium, but the pills contain substantial amounts of fentanyl, often enough so that 1 or 2 of the pills is enough to cause death.

That’s very important because beyond the younger, opiate-dependent population, new data suggest that the average age of a person having an opiate overdose is 75 years. Older Medicare and Medicaid recipients are using the internet to buy pain medications because they find low prices and
CARDIOVASCULAR / CHRONIC CONDITIONS

some are receiving fentanyl-laced pills and dying. The internet is now contributing to drug abuse and harming those looking for pain relief.

**McCarberg:** Substance abuse disorders discovered in people over the age of 60 years are unbelievably rare. But you’re describing a whole different paradigm: an older population looking for less expensive alternatives to pain medications dispensed at the pharmacy who don’t realize how dangerous this is. And they are dying. This is why it’s so important that we have a mechanism for treating that patient population as well as preventing them from getting the medication from an unreliable source.

**Buffington:** The issue is also compounded by the polypharmacy prevalent in individuals in this age group, which already impacts patient safety. Then you look at the illicit, clandestine production for many of these products, masked to look like commercially available prescription medications and now may contain synthetics beyond fentanyl as well, such as carfentanil, remifentanil, and sufentanil. These agents are attractive to those selling illicit substances because very small quantities can produce a substantial effect in terms of potency—and that is what also causes them to be lethal.

**Torrington:** Let’s move on to ways that we can help protect our patients from the flood of fentanyl-contaminated drugs in the U.S. What is your experience with naloxone? What is your opinion about use of naloxone for overdose prevention?

**Kosten:** In Texas, most of the overdoses have fentanyl in them, which means one dose of standard naloxone 0.4 mg given intramuscularly or even 2 mg given intranasally is not going to be enough to override that overdose. Often it takes two, three, sometimes four doses of naloxone to revive the person. It’s causing budget problems for police to the extent that if they are seeing someone with a third overdose, they won’t treat them because they can’t afford it.

Some of the newer naloxone products are larger doses — 8 mg intranasally — and that will need to become the standard because fentanyl is everywhere.

**Buffington:** There are data that support that need for larger doses, too. As the potency of fentanyl products has increased, some studies are tracking upward of five administrations of naloxone to reverse the overdose effects. Fentanyl is absolutely a driver and is creating a patient safety need. The times have changed based on what’s available in the marketplace.

In the clinical arena, when you look at practices that are prescribing naloxone with simultaneous education for the patient and family and caregivers, there is actually a decrease in the number of acute events. Whether there is a direct patient safety issue for the prescribed medications or the risk of a household member gaining access to or using the medication

**“Naloxone can be lifesaving but in order for naloxone or drugs like it to be widely beneficial, they have to be in patients’ hands and patients have to understand how to use them.”**
illicitly or inappropriately, there is a significant benefit to having the naloxone in the home, to getting naloxone into the hands of families who have patients with opiates at home.

McCarberg: The Food and Drug Administration, the Centers for Disease Control and Prevention and the American Medical Association all requested a higher dose. Imagine this from a patient perspective. The patient has a box of Narcan with two doses at home. They end up giving both doses because the first gets no response. EMS may have some, but they haven’t arrived yet. And now, there is loss of life because even though you had the product on hand, the dose was inadequate. It is even more important that we have the larger dose available.

Torrington: Are there limitations to using naloxone to reverse opioid overdose?

Kosten: Many people are using multiple drugs when they are overdosing. The most common are benzodiazepines or alcohol with the opiates. It’s important to recognize that naloxone does not reverse sedative overdose or alcohol overdose. If the patient starts to revive after naloxone is given, but then seems to be drifting away again, it may, in fact, be from concomitant benzodiazepines. These are important common combinations to consider, and the FDA of course recognized that with the new label warnings for the benzodiazepine class.

In addition, we always think of fentanyl as a short-acting drug but it’s not for anyone who is a chronic user because it’s very lipid soluble. The half-life of fentanyl when you give an acute dose and how long it’s going to last if you’ve been chronically using it are vastly different. Naloxone is a very short-acting drug. This is a critical lesson we’re learning with these fentanyl overdoses. When EMS gets there, the person is back in overdose again. Even though they were given something that appeared to be reviving them, it didn’t last long enough.

McCarberg: You have to emphasize to the family and the patient that the elimination half-life of the Narcan (naloxone), depending on how it’s given, can be long — an hour or two — but the effective half-life — how long it actually reverses the overdose — can be very short, 4 to 5 minutes. That may be enough time to call 911 but the patient can’t be left alone for long. Often, a patient, once awake, is reluctant to have anyone call 911 because of the cost or the fear of stigma because now “everyone will know I overdosed.” We have to emphasize to the family that if they don’t call 911, their loved one may die and explain why.

Torrington: Finally, how can we best advance education on treating pain? On opioid use disorder? On the availability and importance of naloxone and how it is used?

McCarberg: First, I would like to make a plea to primary care to be more mindful of the fact that we
are undertreating pain. We need to provide solutions that are more comprehensive psychologically, biologically, in all domains of treating pain.

For the past decade we have opted for an obvious and quick solution by prescribing opioids to treat pain and we got into trouble. Then, we withdrew that medication and didn’t really address the underlying chronic low back pain from the failed back surgery or the fibromyalgia or the chronic daily headaches or the irritable bowel. We need to pay more attention to what other options patients have available. We need to address the pain and if we do that, it’s less likely patients will go to the street or the Internet to find pain medicine.

Second, in California where we are required to offer a naloxone prescription when we prescribe an opioid or benzodiazepine there is often no education provided along with it. The patient and family leave without having a longer visit about how dangerous these drugs (opioids) are, how readily available medication is on the Internet and how dangerous it is to consider that route. They should know that the chance of dying from an unintentional overdose is much higher with a medication obtained that way. They should understand why they are being offered naloxone and become very comfortable with how to use it.

**Buffington:** From a pharmacist’s perspective, we have the benefit of having that full (electronic) medication profile in front of us and can look for other risk factors when dispensing a prescription. You can highlight for the patient potential problems with other medications and also help them realize that they need to respect pain medications for their potency. You can acknowledge that there are ways to reduce the opiate burden with over-the-counter analgesics and nonpharmacologic methods. You can also educate them on the importance of how properly to administer naloxone and the role that it plays in safe use of opioids.

**Kosten:** From my perspective as a psychiatrist, I think the recognition of comorbid psychiatric disorders among patients who have substance abuse just cannot be emphasized enough. The patients who I typically see come in saying they have or a family member says they have a substance abuse problem and they want me to fix it. Most frequently the individual does not have a substance use disorder. What the person has is serious depression and is, in fact, self-medicating.

Treating those depressive disorders is key. If you only take care of the substance abuse and you don’t do anything about the comorbid psychiatric disorder, you’re bound to fail. You have to treat them both.

We have enough clinicians who can provide interventions (medication-assisted treatment, eg, buprenorphine), but we don’t have them treating enough patients. More providers need to be engaged. They have to appreciate that substance abuse and major psychiatric disorders are not totally divergent, but unfortunately are totally convergent and come together. You can die of suicide. You can also die of an overdose just as easily and a whole lot more quickly.

**Torrington:** If I could summarize this excellent conversation in just a few sentences, I would say first that opioid overdose is real and it is prevalent. It is now powered mostly by synthetic fentanyl products, which have completely taken over the illicit drug market, so pain medications ordered from the Internet or obtained from street dealers are likely to contain fentanyl. It is incredibly dangerous.

Second, naloxone can be lifesaving but in order for naloxone or drugs like it to be widely beneficial, they have to be in patients’ hands and patients have to understand how to use them. We need to work on increasing access and education to save lives, our primary job. I want to thank each of you so much for your time and attention and the expertise that you’ve offered.

“As the potency of fentanyl products has increased, some studies are tracking upward of 5 administrations of naloxone to reverse the overdose effects. Fentanyl is absolutely a driver and is creating a patient safety need.”
William Baker, D.O.

Family physician and cowboy action shooter

by Todd Shryock Managing Editor

William Baker, D.O., is a family medicine physician in Las Cruces, New Mexico, and a cowboy action shooter. Baker sat down for an interview with Medical World News® (MWN) to talk about cowboy action shooting and the value of hobbies for physicians. The transcript below was edited for length and clarity. Visit Medical World News® for the full video interview.

MWN: What is cowboy action shooting?
Baker: Well, in cowboy action shooting, there are two versions. There is mounted shooting, which is on a horse, and then what I do is shoot on the ground. We’re shooting steel targets. It’s a variety of things. We shoot two pistols, a rifle and a shotgun.

MWN: How many different targets are there and how far away are they?
Baker: Pistol targets may be as close as 2 yards or they may be as far as 10 to 15 yards and our rifle targets go out to as far as 15 to 17 yards, and shotgun targets are about the same distance. Typically, you’ll have five rounds in each pistol. So that’s 10 rounds, and rifle will typically have nine to 10 rounds. And then shotgun you may shoot anywhere from two shotgun shells to 10 shotgun shells; it depends on who sets the target array up and how they want you to shoot it.

MWN: Is there a time limit? Is this a speed and accuracy contest? Or just accuracy?
Baker: It is speed and accuracy. Accuracy is to just hit the steel target. You don’t have to hit it in the bull’s-eye. You just have to hit it.

MWN: So how did you get started in this?
Baker: I took care of a patient a long time ago — this was in the mid-‘90s — who had a spinal cord malignancy, and unfortunately he passed away from that. And about six months after his death, his brother called me and asked if I was going to be in the office at the end of the day. I said I would be, and he said, “Well, my brother, I was finishing up his estate and he asked me to bring you something.” I told the brother that I took care of the other brother basically for free because he was destitute at the time that he was in trouble and I said I don’t require any repayment. He said, “No, my brother really wanted you to have this.” So his brother brought me a single-action Colt revolver. And his brother had made the pistol grips for that revolver himself for the person who had expired. So that has quite a bit of meaning to me. But in the meantime, I was reading a magazine at that time, which would have been about 1999 or so, and I saw an article about cowboy action shooting. I looked into it, and there was a small club north of us about an hour. I went up and watched and I thought that was fun. I actually had most of the clothing because I had shown horses and I still show horses at this time. I had some of the firearms; I just had to buy a few extras. I got interested in it and it turns out to be a lot of fun.

MWN: You said you have horses but you don’t do the mounted shooting at all?
Baker: Part of the reason is, you need to have a horse you can shoot off of. And what I was told a long time ago, you can shoot off any horse once, but it’s the second time that provides the entertainment.

MWN: How long have you been doing this competitively?
Baker: I’ve been doing this competitively since about 2002. And I’ve enjoyed doing it, though last year with the COVID-19 issues, matches have been real limited and rare. Nationals were canceled in
2021, and world championships were canceled in 2020. They did hold them last year in Indiana but for me, that’s quite a lot of travel, so I did not make nationals or world championships last year. But I’ve gone to the world championships pretty frequently over the last probably 15 years.

MWN: We tend to think cowboys are just American, but it sounds like there are people from everywhere that are enjoying this.
Baker: There are. I’ve met people from New Zealand, Australia, France, Italy, Slovakia, Norway, Canada, Japan and then from all over the United States.

MWN: Is there any country that’s really good at producing really good cowboys?
Baker: You know, every one of them has very good cowboys that are very tough shooters. And we do compete in different categories. My category I shoot is classic cowboy, which means that I dress up like a cowboy, with the chaps, with the roping cuffs, with the spurs, with the felt hat, I wear the vest, all that stuff. And it’s not age based, so I have to shoot against people who are anywhere from 18 to 100 if they’re in the class.

MWN: How does this help you relax after a busy day at the practice?
Baker: It just takes my mind away from all the stressors that I have in the office because I have a fairly busy office practice, and not only dealing with patients — dealing with administration, dealing with finances, all that stuff. This just allows me to decompress a little bit and I think about something completely different.

MWN: What else would you tell people about cowboy action shooting?
Baker: Well, the thing that’s fun about this activity is that everybody that shoots it has a good time. We laugh, we smile. There are people from all walks of life. I’m a physician, but I’ve met people who do everything, and we all have a good time. There’s nobody winning a Cadillac with this. We’re not making a putt that’s going to pay us a million dollars. It’s just fun.
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