

RETHINKING
CONCIERGE
MEDICINE

P. 11

**MALPRACTICE RISKS** 

WOULD YOU **REPORT** AN IMPAIRED PHYSICIAN?

THE PHYSICIAN SHORTAGE



## HELP SHATTER HCV BY LINKING YOUR PATIENTS TO CURE



#### A PROMPT, QUALITY REFERRAL IS VITAL TO GIVE YOUR PATIENTS THE BEST CHANCE OF BEING CURED.1

Your role in HCV makes an impact on patients' lives.

Cure, or sustained virologic response (SVR12), is defined as undetectable levels of HCV in the blood at 12 weeks after completion of therapy. 1.2.

References: 1, AASLD, IDSA, IAS-USA, http://www.hcvguidelines.org. Accessed September 21, 2017. 2. HHS/FDA/CDER. Guidance for Industry. Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment. November 2017. 3. Holmberg SD et al. N Engl J Med. 2013;368(20):1859-1861. 4. McGowan CE et al. Liver Int. 2012;32(suppl 1):151-156.



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AS MANY AS 1/3 OF THOSE WHO TESTED HCV **POSITIVE** DID NOT RECEIVE FOLLOW-UP CARE<sup>3</sup>

TREATMENT DELAYS CAN **INCREASE THE MORBIDITY** AND MORTALITY RISKS OF HCV1



#### TAKE ACTION: LINK ALL OF YOUR DIAGNOSED **HEPATITIS C PATIENTS TO CARE**

**Inform and educate** your patients that HCV often can progress without symptoms and that the earlier treatment is initiated, the more likely they can achieve cure1



Find and schedule the appointment with a provider who treats HCV and is conveniently located for your patients



Follow up to ensure the patient saw a treatment provider because 25% to 50% of HCV patients miss their first appointment4

Consider treating HCV in your practice to help mitigate drop-off in follow-up care





Find information, tools, and educational resources on screening, diagnosing, and referral at HCVcanbecured.com/J13 or download the **RETHINK HCV app** from the App Store or Google Play. FROM THE DESK OF LESLIE KANE, EDITOR-IN-CHIEF

# HAVE DEMANDS ON PHYSICIANS GONE OVER THE TOP?



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Medscape Business
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THE DOCTOR VISIT IS A CORNERSTONE OF A PATIENT'S HEALTH CARE.

Lately, physicians are

being asked to talk with their patients about more than just medical concerns. Some agencies and organizations say that the physician's office is the only place where some patients can get help and information on a range of issues related to the public good, such as domestic abuse, gun safety, keeping prescription drugs away from small children, anger management, and bullying.

Physicians have told me that they've been advised to talk with patients about backyard pool safety, the importance of wearing seat belts, other home hazards, and more—all in the name of public health.

Some physicians are comfortable with this expanded scope of responsibility. Others feel that those subjects dilute the doctor's ability to focus on health care. They also point out that discussing these additional topics is difficult

amid devoting time to paperwork, quality reporting, productivity targets, EHR checklists, complex medical issues, and insurance claims.

As demands on physicians grow, the frustrations and pressure are pushing physicians over the top. Dissatisfaction and burnout are rampant.

A small percentage of physicians have adopted a concierge model that allows them to practice medicine the way they choose. This concept has been evolving over recent years and has become more palatable to some.

To see some of the new ways that doctors are running concierge practices, take a look at our feature article, "Concierge Practice: Could the New Models Be Right for You?" And for more information on this type of practice and other ways to lessen frustration and burnout, visit medscape.com/businessmedicine.

- Leslie Kane

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#### MEDSCAPE NATIONAL PHYSICIAN BURNOUT AND DEPRESSION REPORT 2018

## **HOW SEVERE IS PHYSICIAN BURNOUT?**

Burnout continues to be a pervasive issue among physicians. This part of Medscape's annual Physician Lifestyle Report focuses on their responses to our survey questions about burnout and depression. How prevalent are these factors and how do they affect physicians' lives? More than 15.000 physicians from 29 specialties responded. Check out the full report at medscape.com/2018-lifestyle-burnout-depression.

#### > WHICH DOCTORS ARE **MOST BURNED OUT?**

- 1. Intensivists (48%)
- 2. Neurologists (48%)
- 3. Family physicians (47%)
- 4. Ob/gyns (46%)
- 5. Internists (46%)
- 6. Emergency medicine physicians (45%)
- 7. Radiologists (45%)

WHO IS MORE **BURNED OUT. MEN** OR WOMEN?

#### > TOP 5 REASONS **FOR BURNOUT**

- 1. Too many bureaucratic tasks (56%)
- 2. Too many hours at work (39%)
- 3. Lack of respect from employers, colleagues, or staff (26%)
- 4. EHRs (24%)
- 5. Insufficient compensation (24%)

#### > HOW MUCH ALCOHOL DO PHYSICIANS DRINK?

- 1. Do not consume alcohol at all (22%)
- 2. Less than one drink a week (27%)
- 3. 7 or more drinks each week (8%)

#### WHICH SPECIALISTS HAVE THE **LOWEST RATES OF BURNOUT?**

Plastic surgeons 23%

Dermatologists 32%

Pathologists 32%

Ophthalmologists 33%

#### MAIN WAYS PHYSICIANS COPE WITH BURNOUT \*

Exercise 50%

Talk with family/close friends 46%

Sleep **42**%

Isolate from others 36%

Eat junk food 33%

\*Note: Respondents could choose more than one answer

#### **HOW MUCH VACATION DO PHYSICIANS TAKE EACH YEAR?**

More than four weeks 18%

Three to four weeks 49%

Two weeks or less 33%

they are both burned

out and depressed.

#### **SOME DOCTORS' ADVICE ON PREVENTING BURNOUT:**

- Count your blessings.
- > Don't watch the news. Okay, maybe a little.
- > Don't take your computer home.
- > Make yourself happy and do the job.

#### PHYSICIANS ARE SEEING MORE **PATIENTS AT WORKSITE CLINICS**

Physicians may soon have an additional work option to choose fromonsite medical clinics at workplaces are making a comeback, as employers increasingly see this as a cost-effective health care option for employees.

Companies offering this service typically include primary care physicians as well as specialists and other health care providers.

Larry Boress, head of the National Association of Worksite Health Centers, said that a survey showed that about 30% of U.S. businesses of all sizes offered medical care for employees. In 2018, 50% of companies will offer this service, with an additional 11% saying they are considering opening an onsite clinic by 2020, Boress told The Wall Street Journal.

#### **SPEAKING OUT AGAINST CLINICIANS** WHO PARTICIPATE IN TORTURE

More physicians have come out strongly against clinicians who participate in torture for any reason.

It is unethical for health care professionals to participate in torture, facilitate it, allow it to continue, or be present during torture, wrote Zackary Berger, MD, PhD, associate professor at Johns Hopkins School of Medicine and primary care physician, and his colleagues in an analysis published in the BMJ.

The issue came to the forefront after a 2016 release by the CIA of previously classified papers showed that the CIA conducted experimental research to find out whether torture could break the

resistance of detainees being interrogated. Health care workers took part in these experiments to define the torture subjects' thresholds of pain and suffering.

"Medical participation in torture has taken place throughout the world and was a prominent feature of the U.S.

interrogation practice in military and Central Intelligence Agency (CIA) detention facilities in the years after the attacks of Sept. 11, 2001. Little attention has been paid, however, to how a regime of torture affects the ability of health professionals to meet their obligations regarding routine clinical care for detainees," wrote Dr Berger and his colleagues.

Finally, the authors urge professional associations of physicians, psychologists, psychiatrists, and other health care professionals, as well as licensing authorities, to sanction health care professionals who have participated in torture.



#### > MEDICARE WELLNESS VISITS CAN **INCREASE PHYSICIANS' REVENUE**

Almost one half of physician practices may not be taking advantage of an opportunity to generate revenue by providing annual wellness visits to Medicare patients, according to a new study published in Health Affairs.

"Adoption of the annual wellness visit may benefit practices financially, yet half of them are missing out on these benefits—particularly practices that disproportionately care for medically and socially complex patients," the authors wrote.

The study, conducted by Harvard Medical School researchers using national Medicare data, found that in 2015. about 51% of practices did not provide annual wellness visits. whereas about 23% provided the visits to at least one quarter of eligible patients.

Practices that scheduled annual wellness visits rather than the typical problem-based

visits saw increases in primary care revenue because Medicare pays more for such a visit. said the study's researchers.

The average reimbursement for an initial annual wellness visit is \$172 per patient. For all subsequent visits the average reimbursement per patient is \$111.

Why are so many primary care practices missing out on the wellness visit? One reason may include the wellness visit's complex and confusing requirements; other reasons may be that for physicians with disadvantaged or high-risk patients, the practice may be busy caring for patients with more critical health needs.

## TO HUG OR NOT TO HUG A PATIENT?

PHYSICIANS DIFFER ON THE RIGHT BEHAVIOR BY SANDRA LEVY

here is a new caution affecting personal interactions in the physician's office. Given the numerous recent high-profile accusations of alleged sexual harassment and inappropriate behavior, people are concerned that formerly "acceptable" behavior could now land them in trouble.

Doctors care about their patients, and a hug is a common physical expression of caring. But is it appropriate to hug a patient? Hugging patients comes naturally for some physicians, especially when the patient has a terrible disease, is grieving, or is lonely and needs moral support. A recent Medscape article titled "Should Doctors Hug Their Patients?" asked this question and generated heartfelt responses.

**66**HUGGING THE PATIENT MAY COME BACK TO HAUNT YOU. YOU'RE NOT A MIND READER. YOU **DON'T KNOW HOW THE PATIENT WILL REACT** OR WHAT THE PATIENT THINKS ABOUT YOU REACHING OVER AND HUGGING THEM. 99

-AN OB/GYN

"If my patient asks me, 'Doc, can I give

you a hug?' my answer will always

be 'yes.' However, it will be a three-

second hug and nothing more."

-A PHYSICIAN

"I began hugging my HIV/AIDS massage therapy clients in 1995 when many health care providers were terrified to touch them. That experience has made me a 'hands-on' physician today." —A FAMILY PHYSICIAN



#### SO NOW WE NEED 'GUIDELINES' FOR HUGS? THAT IS PATHETIC.

SO MANY OF OUR ELDERLY PATIENTS NEED AND ASK FOR HUGS AS A GREETING OR. MORE OFTEN. A GOODBYE."

-A PHYSICIAN



"I hug every one of my patients and kiss most. That's my culture. It's what 'feels right' to me. That's my expression of sympathy/ empathy—of 'I am in this with you."

—A PHYSICIAN

"I offer hugs in appropriate situations, and I have many long-term patients for whom this is a natural gesture of greeting or farewell. It is common for me to encounter patients who share enormous pain . . . marital infidelity, aging parents, deaths in the family, job stress, errant teenage children . . . during the course of their appointment . . . patients who feel comfortable being honest and vulnerable with me." -AN OB/GYN

66NO, WE SHOULD NOT **EVER HUG PATIENTS. IT IS** AN UNEQUAL RELATIONSHIP AND CAN BE MISCONSTRUED. SHAKING HANDS, SPEAKING KINDLY, AND SPENDING TIME ARE PROPER, AND PRACTICING THE LOST ART OF LISTENING. "

—A HEALTH CARE PROVIDER

"The cons include the following: The recipient calls the police and files charges of sexual battery. The DA chooses to prosecute. The patient files a lawsuit. The medical

—AN EMERGENCY MEDICINE PHYSICIAN

"YES. TOUCHING THE PATIENT APPROPRIATELY IS THERAPEUTIC. SIDE HUGS ARE HIGHLY ADVISED. AND NEVER BELLY HUGS." -A GASTROENTEROLOGIST

board revokes the

doctor becomes

bankrupted from

doctor's license. The

the costs of his legal

award. loss of income.

defense, plaintiff's

and restriction from

practicing medicine."

**66** I WAS ALWAYS TAUGHT A HUG CAN BE MISCON-STRUED. I STILL STAND BY THIS CONCEPT. IF SOMEONE HAS A LOSS, I WILL TOUCH THEIR ARM AND EXPRESS MY SYMPATHY. 99

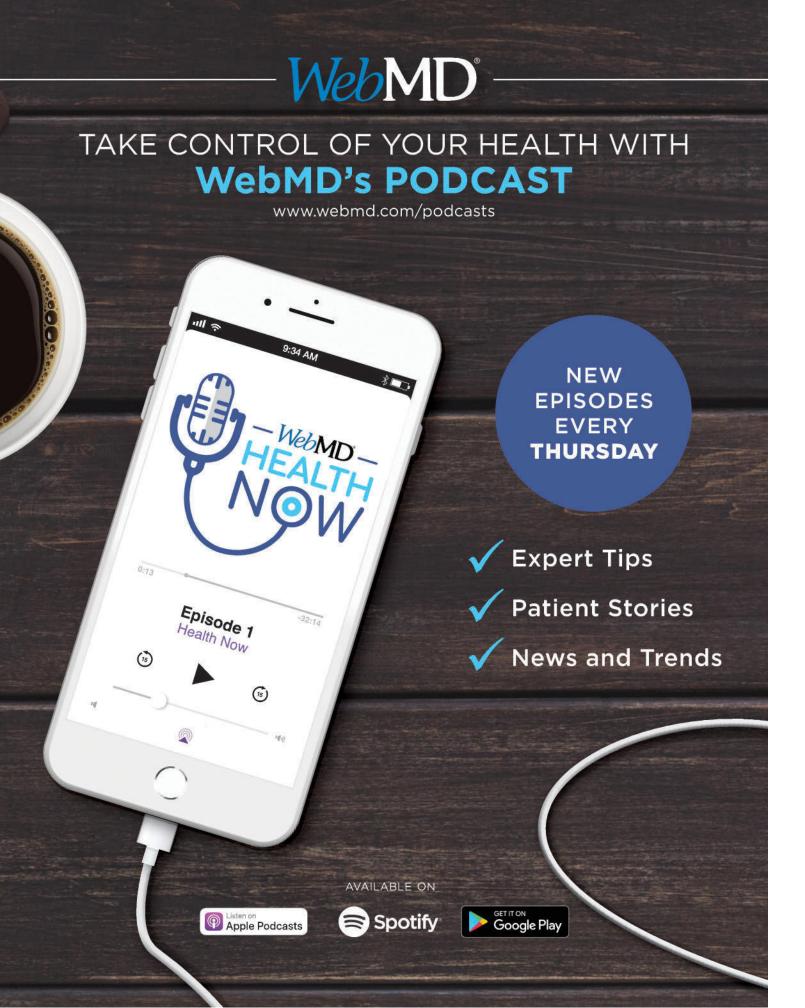
**66** I SHAKE HANDS OR SAY A TRADITIONAL 'NAMASTE' WITH **BOTH HANDS TOUCHING AS** IN PRAYING. WHICH CONVEYS ALL OF MY GOOD FEELINGS. THOUGHTS, AND WISHES TO MY PATIENTS EFFECTIVELY. 99

**66** I TRY NOT TO HUG ANYONE WHEN I AM IN A PROFESSIONAL SET-TING. I TRY NOT TO EVEN SHAKE HANDS IN THAT I **CONSIDER THAT ACTION** A BUSINESS-TO-BUSINESS **RELATIONSHIP (SEALING THE** DEAL WITH A REALTOR, FOR EXAMPLE). 99

"I have grappled with this question over the years, but I mostly settled on total avoidance of embrace. An occasional hug when there has been a death in a patient's family, but I recall this as once every few years."

-A DERMATOLOGIST

8 \\ BUSINESS OF MEDICINE





## CHARGING MEMBERSHIP FEES OF MORE THAN \$100 A MONTH WHILE STILL GETTING INSURANCE REIMBURSEMENTS, the classic concierge practice allows mostly primary care physicians to provide more comprehensive services to a relatively small panel of 50–1,000 patients.

Now, however, new groups of physicians are changing the original concierge model and recreating it in new ways. For example:

- Specialists, large group practices, and hospital-employed physicians are offering concierge relationships for some of their patients; the rest retain a traditional arrangement.
- Other physicians have reduced the membership fee, dropped insurance altogether, and created a less expensive practice model that can appeal to patients with less money.
- Start-up companies are repackaging the membership model, pairing it with high-deductible insurance, and selling it to employers as a more effective way of covering their workers.

Some proponents envision this consumer-based model as a way to replace our insurance-based system with a consumer-based system and save health care from escalating costs. With the degree of discontent many physicians feel toward the health care profession, these "new, improved" models may appeal to a growing number of doctors.

#### THE HYBRID MODEL

Physicians have been tinkering with the concierge model for a long time. For example, many of them keep patients who won't convert to the membership model—either because they don't want to lose those patients or because they can't find enough memberships to replace them.

According to a 2016 survey, only 30% of physicians who take any kind of membership fee have all of their patients under that model.

This approach, called "hybrid concierge," is now being adopted by specialists who have been shut out of the concierge phenomenon, according to Wayne Lipton, CEO of Concierge Choice Physicians, a concierge care consultant in Rockville Centre, New York.

Seeing only concierge patients on a long-term basis is impossible for specialists, who provide episodic care

to most of their patients. But many specialties do see some patients on a long-term basis and function in many ways as their primary care provider, Lipton says.

These specialties include cardiology, gastroenterology, pulmonology, rheumatology, and endocrinology. Lipton says that cardiologists became interested in concierge as a new form of income, as reimbursements have declined in the past two years or so. "We've also seen more interest among gastrointestinal [GI] docs, who are shifting from scoping to doing ongoing GI issues," he says.

These specialists convert a small but significant portion of their patients to concierge—something like 2%–3%, Lipton says. According to a recent assessment by the editor of *Concierge Medicine Today*, specialists make up almost 10% of concierge practices, and interest in concierge is growing "moderately" among specialties.

According to a 2015 study, direct primary care (DPC) practices charged patients an average of \$77.38 per month, compared with \$182.76 for concierge practices. DPC practices use a retainer model.

electronic medical record systems can be much simpler because DPC physicians aren't using them to bill insurance.

Some doctors start a DPC practice but diverge from the standard model. For example, they don't want to dismiss longtime patients who won't convert to DPC, or fire staff who aren't needed in direct care. Also, as in Dr Wood's case, they may not be able to find enough patients to support a pure DPC model.

Such practices become hybrids, serving two groups of patients—those paying through membership fees and those billed through their insurance.

Hybrid DPCs may not be a good business model for individual physicians, but they have turned out to be a great business model for DPC companies, which match employers who want DPC coverage with clinicians who can provide it.

Physicians who had no interest in DPC may consider setting up a DPC hybrid or working fulltime in DPC. A company will educate them and their staffs on how to provide services and back them up after they start.

Some DPC companies offer full-time employment for physicians. Paladina Health, for example, pays "a flat salary and incentivized through bonuses on health outcomes, patient engagement, and patient satisfaction," according to its website.

Others actively recruit new doctors who then set up DPC practices. For example, MedLion has reportedly been helping new primary care providers start their own practices with incentives like helping them pay back student loans and choose a location.

#### THE ACA EFFECT

Dr Forrest says removal of the ACA mandate to buy health insurance, which was part of President Trump's tax bill passed in December 2017, will be a boon for DPC.

In 2019, when the ACA mandate ends, insurers will be allowed to offer policies that don't comply with the ACA's mandate for minimum essential coverage, which requires coverage of a standard set of services, Dr Forrest reports.

When that happens, insurers can offer stripped-down policies that cost about one quarter of what they cost

today, he says. With these savings, employers and people who have to buy their own insurance easily have enough money to buy DPC memberships.

These memberships will give consumers access to primary care that they can't get with their high-deductible policies—unless, of course, they reach their deductible, which may never happen unless they get very sick, given the current stratospheric amounts of deductibles.

Lipton, the concierge consultant and an outspoken critic of DPC practice, feels a little unsettled by these changes in the health care market.

"Obamacare was all about getting people on insurance, but direct pay is all about reducing your use of insurance and relying on your own personal funds to cover your health care," he says. "That works for wealthier people, such as concierge members, but it doesn't work for people who don't have any money to spend on health care."

As deductibles go yet higher, DPCs are expected to be even more attractive to consumers. "We're going to see more of this growth," predicts George Claassen, an employee insurance expert in Methuen, Massachusetts.



#### **DPC OPTIONS**

DPC practices can reduce expenses by eliminating insurance reimbursements. Even though this means giving up another form of income, it actually saves a great deal of money because billing operations are very expensive—from coding to compiling bills based on codes and dealing with insurers.

Dr Forrest says DPC doctors can potentially get discounts of up to 30%–60% for malpractice coverage because closer relationships with patients lowers the risk of being sued. He adds that

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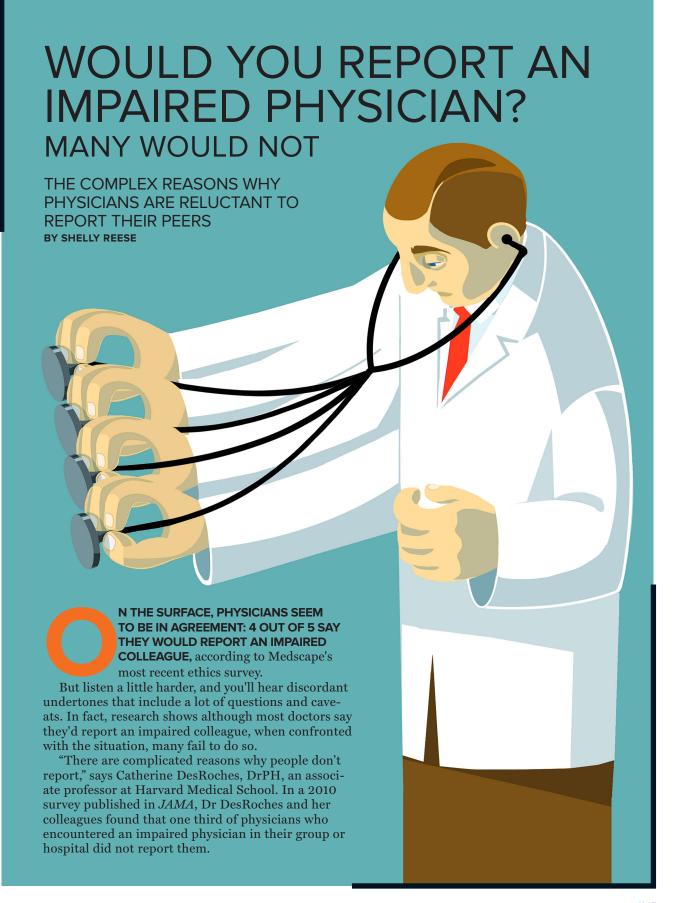


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HY ARE SO MANY PHYSICIANS RELUCTANT TO REPORT THEIR **IMPAIRED PEERS?** It's complicated by the fact that many physicians feel that they are taking the positive and more helpful

course of action by not reporting.

More than 10% of physicians will develop an addictive disorder over the course of their career, and

Many physicians at some point in their careers will encounter a colleague whose performance is impaired

approximately one third will have a condition that could impact their ability to practice with reasonable skill and safety at some point in their career, according to the Federation of State Physician Health Programs.

Given those high percentages, there's a high probability that many physicians at some point in their careers will encounter a colleague whose performance is impaired by drugs, alcohol, or illness. Would they report them? Nearly 4 out of 5 (78%) of the 7,500 physicians responding to Medscape's most recent ethics report say they would. Another 18% aren't so sure. A small minority (4%) say they would not.

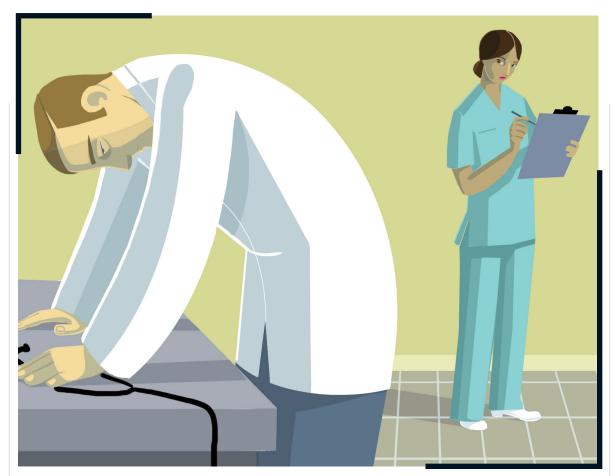
Doctors who say they might not report a colleague provided a number of reasons.

#### **HOW IMPAIRED IS IMPAIRED?**

Many doctors imply there would be some sort of calculus to their decision: "How impaired?" "How occasionally?" "Has he or she produced harm?"

Still others note that their decision would be based on their own professional assessment of a colleague's impairment. "Depends on their ability to perform as required," writes an anesthesiologist.

A mental health professional says that the decision depends on how it "impacts their professional capacity to function."



"Depends on my confidence level in their impairment," notes a pathologist.

#### **CAUSE OF IMPAIRMENT**

Many physicians tell Medscape that their decision to report a colleague would depend on the cause. "Drugs or alcohol, probably, but if it was related to mental health, I won't report them," writes one pediatrician.

"Mild impairment by illness is one thing, but

gross impairment by drugs/ alcohol should be reported," writes another.

"Definitely for alcohol or drugs; for illness, I would first encourage them to take time off and get treatment," says a mental health professional.

That distinction is troubling, says Lisa Merlo, PhD, an associate professor in the department of psychiatry and the University of Florida College of Medicine and research director for Florida's Physician Health Program. "I think there is still some lack of understanding about what is impairing," says Dr Merlo, who says that training pertaining to substance-use disorders should be incorporated into medical education.

#### **AND DISTRUST** OF THE SYSTEM

Many physicians say they would hesitate to report a

## **PROFESSIONALISM**

that the colleague would be severely punished or would not receive the help they needed. In a similar vein.

colleague out of concern

many physicians say they don't trust the system to address a colleague's impairment fairly and effectively. A general surgeon refers to formal reporting as "unleashing the hounds," and an internist states that "the system is too punitive as it stands without me adding to physician suicide numbers."

Even some physicians who have reported impaired colleagues in the past lament that they did not feel they could predict the consequences of their actions. "The problem is the jeopardy in doing this. The problem is the authorities and how they handle it," writes an orthopedist who reported an impaired colleague. An emergency medicine physician agrees: "I have [reported an impaired colleague]; however, I feel the physician's problem was poorly handled by the state board. He did not get the treatment he needed, and he lost his license. Very sad case.'

#### **HELPING PHYSICIANS COME FORWARD**

Even though a majority of Medscape respondents say they would report an impaired colleague, chances are that if the situation occurred, many would not, speculates Dr DesRoches.

"When you ask people a hypothetical question, you'll often get an idealized answer," Dr DesRoches says. One third of the physicians she surveyed for the 2010 JAMA study who had direct personal knowledge of an impaired colleague during the previous three years failed to report them because theu:

- + Believed someone else was taking care of the problem (19%)
- + Didn't think reporting the problem would make a difference (15%)
- + Feared retribution (12%)
- + Felt it wasn't their responsibility to report (10%)
- + Worried that the physician would be excessively punished (9%)

"What surprised me was how few physicians said they felt prepared to deal with this situation," she says. "Normally, physicians are a very confident group, but only two thirds of respondents felt they were prepared to deal with the situation, so it seems like there's an opportunity to start early and prepare

physicians in residency and medical school to help them understand their responsibility and to act on it."

Thomas Gallagher, MD, associate chair of the department of medicine and a professor in the department of bioethics and humanities at the University of Washington, says that means reframing the definition of professionalism to better focus on patient safety. Medical schools need to train students to speak up, and health care institutions need to improve their peer review processes.

"If we could communicate how peer review works, physicians will have fewer reservations about coming forward," Dr Gallagher says.

Peer reviewers also need to communicate results, says Dr DesRoches. In today's rapidly changing health care environment, physicians "feel under siege," she says. "They're burned out and fatigued, and the perception that reporting an impaired colleague amounts to 'unleashing the hounds' plays into that sense of feeling under siege."

TO SEE MORE ABOUT DOCTORS' ETHICAL DILEMMAS, SEE MEDSCAPE'S PHYSICIAN ETHICS CENTER: MEDSCAPE.COM/RESOURCE/ETHICS



# WHEN MISSING A 'ZEBRA' COULD LAND YOU IN COURT

ne of the most famous axioms in medi-

BY MARK CRANE

cine is, "When you hear hoofbeats, think horses, not zebras."

Every medical school student is taught that most diagnoses are more likely to involve common conditions and diseases than rare ones. Focus on the likeliest possibilities rather than the obscure ones.

That makes good sense—except when the physician is confronted with a patient who may have one of 7,000+ rare diseases listed by the National Institutes of Health, each disease affecting fewer than 200,000 people in the United States. Together, rare diseases affect almost 30 million Americans or about 1 in 10 people. Globally, an estimated 350 million people have rare diseases.

Physicians are generally unlikely to face a malpractice suit for misdiagnosing a rare disease. However, even

though a disease might be rare, the results of a delayed or wrong diagnosis can be devastating or lethal. Juries have awarded millions of dollars in cases involving both primary care physicians and specialists. The doctors and hospitals not only missed the right diagnosis, they did too little to find out why the patient failed to improve after their early treatment.

"We just don't get a lot of these claims," says William S. Kanich, MD, JD, chief medical officer for MagMutual, a Georgiabased medical malpractice carrier. "It isn't usually the rare diseases doctors get sued for. It's the common ones—missing heart attacks, appendicitis, cancer, pneumonia, etc."

### MISDIAGNOSIS IS COMMON

"The standard of care in rare disease cases, frankly, is to miss them," says Dr Kanich. "Juries tend to give

Continued on page 21

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  compared to every 8 weeks. Some patients may need every 4 week
  (monthly) dosing after the first 12 weeks (3 months).
- Macular Edema following Retinal Vein Occlusion (RVO): The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly).
- Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR) in Patients with DME: The recommended dose is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 5 injections, followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated in most patients when EYLEA was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).

#### CONTRAINDICATIONS

 EYLEA® (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

#### WARNINGS AND PRECAUTIONS

 Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.



- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA.

  ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

#### **ADVERSE REACTIONS**

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.

#### Please see adjacent Brief Summary.

\*Best-corrected visual acuity.

\*Early Treatment Diabetic Retinopathy Study-Diabetic Retinopathy Severity Scale: an established grading scale for measuring the severity of DR.

Reference: 1. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. May 2017.

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#### REGENERON

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BRIEF SUMMARY—Please see the EYLEA package insert for full Prescribing Information.

#### 1 INDICATIONS AND USAGE

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of

Neovascular (Wet) Age-Related Macular Degeneration (AMD); Macular Edema Following Retinal Vein Occlusion (RVO); Diabetic Macular Edema (DME); Diabetic Retinopathy (DR) in Patients with DME

#### 4 CONTRAINDICATIONS 4.1 Ocular or Periocular Infections

FYLEA is contraindicated in patients with ocular or periocular infections

#### 4.2 Active Intraocular Inflammation EYLEA is contraindicated in patients with active intraocular inflammation.

EYLEA is contraindicated in patients with known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, severe anaphylactic/anaphylactoid reactions, or severe

#### 5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachments, Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments [see Adverse Reactions (6.1)]. Proper aseptic injection technique must alway be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophtha retinal detachment without delay and should be managed appropriately [see Dosage and Administration (2.7) and Patient Counseling Information (17)

5.2 Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA [see Adverse Reactions (6.1)]. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately [see Dosage and Administrat.

5.3 Thromboembolic Events. There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combin group of patients treated with EYLFA compared with 4.2% (12 out of 287) in the control group. There were no reported poembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

#### 6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity [see Contraindications (4.3)]
- · Endophthalmitis and retinal detachments [see Warnings and Precautions (5.1)]
- Increase in intraocular pressure [see Warnings and Precautions (5.2)]
- Thromboembolic events [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience. Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in other clinical trials of the same or another

A total of 2711 patients treated with EYLEA constituted the safety population in seven phase 3 studies. Among those 2110 patients were treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedu have occurred in < 0.1% of intravitreal injections with FYLEA including endoubthalmitis and retinal detachment. The most mon adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment

Neovascular (Wet) Age-Related Macular Degeneration (AMD). The data described below reflect exposure to EYLEA in 1824 patients with wet AMD, including 1223 patients treated with the 2-mg dose, in 2 double-masked, active-controlled clinical studies (VIEW1 and VIEW2) for 12 months

#### Table 1: Most Common Adverse Peactions (~1%) in Wet AMD Studies

Adverse Reactions	EYLEA (N=1824)	Active Control (ranibizumab (N=595)	
Conjunctival hemorrhage	25%	28%	
Eye pain	9%	9%	
Cataract	7%	7%	
Vitreous detachment	6%	6%	
Vitreous floaters	6%	7%	
Intraocular pressure increased	5%	7%	
Ocular hyperemia	4%	8%	
Corneal epithelium defect	4%	5%	
Detachment of the retinal pigment epithelium	3%	3%	
Injection site pain	3%	3%	
Foreign body sensation in eyes	3%	4%	
Lacrimation increased	3%	1%	
Vision blurred	2%	2%	
Intraocular inflammation	2%	3%	
Retinal pigment epithelium tear	2%	1%	
Injection site hemorrhage	1%	2%	
Eyelid edema	1%	2%	
Corneal edema	1%	1%	

<1% of the patients treated with EYLEA were hypersensitivity, retina</p> detachment, retinal tear, and endophthalmitis

Macular Edema Following Retinal Vein Occlusion (RVO). The data described below reflect 6 months exposure to FYI FA with a monthly 2 mg dose in 218 patients following CRVO in 2 clinical studies (COPERNICUS and GALILEO) and 91 patients following BRVO in one clinical study (VIBRANT)

#### Table 2: Most Common Adverse Reactions (≥1%) in RVO Studies

Adverse Reactions	CRVO		BRVO	
	EYLEA (N=218)	Control (N=142)	EYLEA (N=91)	Control (N=92)
Eye pain	13%	5%	4%	5%
Conjunctival hemorrhage	12%	11%	20%	4%
Intraocular pressure increased	8%	6%	2%	0%
Corneal epithelium defect	5%	4%	2%	0%
Vitreous floaters	5%	1%	1%	0%
Ocular hyperemia	5%	3%	2%	2%
Foreign body sensation in eyes	3%	5%	3%	0%
Vitreous detachment	3%	4%	2%	0%
Lacrimation increased	3%	4%	3%	0%
Injection site pain	3%	1%	1%	0%
Vision blurred	1%	<1%	1%	1%
Intraocular inflammation	1%	1%	0%	0%
Cataract	<1%	1%	5%	0%
Evelid edema	<1%	194	194	094

Less common adverse reactions reported in <1% of the patients treated with EYLEA in the CRVO studies were corneal dema, retinal tear, hypersensitivity, and endophthalmitis.

Diabetic Macular Edema (DME). The data described below reflect exposure to EYLEA in 578 patients with DME treated with the 2-mg dose in 2 double-masked, controlled clinical studies (VIVID and VISTA) from baseline to week 52 and from baseline

#### Table 3: Most Common Adverse Reactions (≥1%) in DME Studies

Adverse Reactions	Baseline to week 52		Baseline to week IUU	
	EYLEA (N=578)	Control (N=287)	EYLEA (N=578)	Control (N=287)
Conjunctival hemorrhage	28%	17%	31%	21%
Eye pain	9%	6%	11%	9%
Cataract	8%	9%	19%	17%
Vitreous floaters	6%	3%	8%	6%
Corneal epithelium defect	5%	3%	7%	5%
Intraocular pressure increased	5%	3%	9%	5%
Ocular hyperemia	5%	6%	5%	6%
Vitreous detachment	3%	3%	8%	6%
Foreign body sensation in eyes	3%	3%	3%	3%
Lacrimation increased	3%	2%	4%	2%
Vision blurred	2%	2%	3%	4%
Intraocular inflammation	2%	<1%	3%	1%
Injection site pain	2%	<1%	2%	<1%
Eyelid edema	<1%	1%	2%	1%

letachment, retinal tear, corneal edema, and injection site hemorrhage.

6.2 Immunogenicity. As with all therapeutic proteins, there is a potential for an immune response in patients treated with YLEA. The immunogenicity of EYLEA was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to EYLEA with the incidence of antibodies to other products may be misleading.

the wet AMD, RVO, and DME studies, the pre-treatment incidence of immunoreactivity to EYLEA was approximately % to 3% across treatment groups. After dosing with EYLEA for 24-100 weeks, antibodies to EYLEA were detected in a similar percentage range of patients. There were no differences in efficacy or safety between patients with or without

#### **8 USE IN SPECIFIC POPULATIONS**

#### 8.1 Pregnancy

#### Risk Summary

Adequate and well-controlled studies with EYLEA have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations. A fetal No Observed Adverse Effect Level (NOAEL) was not identified. At the lowest dose shown to produce adverse embryofetal effects, systemic exposures (based on AUC for free aflibercept) were approximately 6 times higher than AUC values observed in humans after single intravitreal treatment at the recommended clinical dose [see Animal Data]

Animal reproduction studies are not always predictive of human response, and it is not known whether EYLEA can cause etal harm when administered to a pregnant woman. Based on the anti-VEGF mechanism of action for aflibercept [se Clinical Pharmacology (12 1) 1, treatment with EYLEA may pose a risk to human embryofetal development. EYLEA should be ised during pregnancy only if the potential benefit justifies the potential risk to the fetus

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

n two embryofetal development studies, aflibercept produced adverse embryofetal effects when administered every three days during organogenesis to pregnant rabbits at intravenous doses ≥3 mg per kg, or every six days during organogenesi at subcutaneous doses >0.1 mg per kg.

Adverse embryofetal effects included increased incidences of postimplantation loss and fetal malformations, including anasarca, umbilical hernia, diaphragmatic hernia, gastroschisis, cleft palate, ectrodactyly, intestinal atresia, spina bifida, encephalomeningocele, heart and major vessel defects, and skeletal malformations (fused vertebrae, sternebrae, and ribs; supernumerary vertebral arches and ribs; and incomplete ossification). The maternal No Observed Adverse Effect Level NOAEL) in these studies was 3 mg per kg. Aflibercept produced fetal malformations at all doses assessed in rabbits and the fetal NOAEL was not identified. At the lowest dose shown to produce adverse embryofetal effects in rabbits (0.1 mg per kg), systemic exposure (AUC) of free affibercept was approximately 6 times higher than systemic exposure (AUC) observed in numans after a single intravitreal dose of 2 mg.

#### 8.2 Lactation

Risk Summary There is no information regarding the presence of aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Because many drugs are excreted in human milk, and because the potential for absorption and harm to infant growth and development exists. EYLEA is not recommended during

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EYLEA and any potential adverse effects on the breastfed child from EYLEA.

#### 8.3 Females and Males of Reproductive Potential

Contraception

Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment, and or at least 3 months after the last intravitreal injection of EYLEA.

Infertility
There are no data regarding the effects of EYLEA on human fertility. Aflibercept adversely affected female and male reproductive systems in cynomolgus monkeys when administered by intravenous injection at a dose approximately 1500 times higher than the systemic level observed humans with an intravitreal dose of 2 mg, A No Observed Adverse Effect Level NOAEL) was not identified. These findings were reversible within 20 weeks after cessation of treatment [see Nonclinical

8.4 Pediatric Use. The safety and effectiveness of EYLEA in pediatric patients have not been established.

8.5 Geriatric Use. In the clinical studies, approximately 76% (2049/2701) of patients randomized to treatment with EYLEA were ≥65 years of age and approximately 46% (1250/2701) were ≥75 years of age. No significant differences in efficacy or safety were seen with increasing age in these studies.

#### 17 PATIENT COUNSELING INFORMATION

n the days following EYLEA administration, patients are at risk of developing endophthalmitis or retinal detachment. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise patients to seek immediate care from an phthalmologist [see Warnings and Precautions (5.1)].

examinations [see Adverse Reactions (6)]. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591

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> Based on the May 2017 EYLEA\* (aflibercept) REGENERON

Continued from page 18

physicians the benefit of the doubt in most cases. The key question for the doctor is: How do you know what you don't know? In the first two years of medical school, we'd often hear about pheochro-

"A doctor isn't required to know everything. That's impossible. But you need to know where to go when you don't have the answer."

mocytoma, a malignancy on the adrenal gland, and other rare diseases. But in 15 years of practice, I've never seen one. It's difficult to diagnose a disease like that. If the patient isn't responding the way you think he should, that's when doctors have to ask themselves, 'What am I missing? What else could it be?"

#### **DOCTORS MAY THINK** THEY HAVE IT RIGHT

No one is exactly sure how often physicians misdiagnose or are late to diagnose medical conditions. "In most diagnostic errors, the physician was pretty sure of what was going on, except it turned out to be something else," says Mark Graber, MD, founder of the Society to Improve Diagnosis in Medicine.

"Most doctors don't even think about their track record in making

diagnoses," he says. "Autopsies have virtually disappeared. Doctors don't get high-quality feedback. Often, you'll never even hear if you injure a patient, who may go see someone

else after you. Few health care organizations are measuring the incidence of diagnostic error in their own practices."

It takes an average of 7.6 years for a U.S. patient with a rare disease to receive the

proper diagnosis, the 2013 Shire Disease Impact Report found. Such patients typically visit up to eight physicians before they get the right diagnosis.

The biggest mistake physicians make is not listening to the patient or his or her family when they say something is wrong, say the experts we asked.

"When the family tells you something isn't right, listen carefully," says Dr Kanich. "If a parent tells me their child isn't well, I tend to believe them. Nobody knows their child better than the parents."

Dr Graber agrees. In the cases he's studied, parents "kept insisting that something was wrong and that the assigned diagnoses didn't seem correct," he says. "We hear this over and over from patients—that they weren't listened to."

#### **RULE OUT THE WORST POSSIBILITIES**

"We don't take malpractice cases just because a doctor made a mistake," says Malcolm McConnell, a plaintiff's attorney in Richmond, Virginia. "Doctors are human. But was the mistake a reasonable one? Did the doctor do a proper differential diagnosis, prioritizing according to the likelihood and severity? A doctor had a duty to rule out potentially lethal or life-changing conditions."

McConnell represented a patient who died from hemochromatosis, a condition in which too much iron is absorbed, builds up in the skin and liver, and can lead to cirrhosis of the liver, cancer, and death.

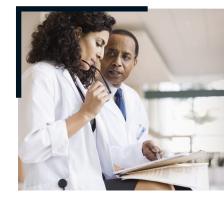
"This patient went to his primary care doctor for routine blood tests at least once a year for 12 years," he says. "On every single study, his liver enzymes were elevated. I don't sav that the doctor had to diagnose hemochromatosis, but he needed to follow up on why the liver enzymes were elevated, which he never did. When the diagnosis was finally made, the patient had cancer and died. If he'd been diagnosed earlier, the condition could have been managed. A confidential settlement was reached."

#### **ENLIST AN EXPERT**

As the other attorneys suggested, physicians must consider the "worst first," says Charles P. Hehmeyer,

a plaintiff's attorney in Philadelphia who specializes in inborn errors of metabolism: "If the problem is most likely to be A, but B or C can kill you, you have to rule them out. A doctor isn't required to know everything. That's impossible. But you need to know where to go when you don't have the answer. If you don't know, don't just assume. Know your own limitations and get an expert to help you.

"Defense attorneys always argue the hoofbeats theory, and it's often effective with juries. While doctors were taught about hoofbeats and horses, they were also taught that if you hear hoofbeats but also see stripes, it just might be a zebra. I speak at meetings for several rare disease organizations. Many parents wear T-shirts that say 'Think Zebras."



#### > HELPFUL RESOURCES:

The National Organization for Rare Disorders

The Genetic and Rare Diseases Information Center

**BUSINESS OF MEDICINE // 21** 

## DR ERIC TOPOL AND DR EZEKIEL EMANUEL THE PHYSICIAN SHORTAGE SOLUTION

EZEKIEL EMANUEL, MD, PhD, oncologist and chair of the department of medical ethics and health policy at the University of Pennsylvania, speaks with **ERIC TOPOL**, MD, editor-in-chief of Medscape, about how he feels the physician shortage issue could be solved.



ERIC TOPOL, MD



EZEKIEL EMANUEL.

Wait time is not a function of doctor supply; it is a function of how you manage doctor time

**DR TOPOL:** Zeke, why don't you give us your own sense about a physician shortage in the United States?

**DR EZEKIEL EMANUEL:** If you look through history, everyone is always predicting that we will have this terrible physician shortage. Yes, there are lots of problems—delays in getting an appointment and spot shortages in certain specialties, especially some pediatric subspecialties. But if you look at the issue of primary care doctors, I think the notion of a shortage is greatly exaggerated. My intuition is that we are just bad at managing time.

> First, we are not maximizing our doctor time. We have doctors doing a lot of things that they should never be doing. They are filling out paperwork and arranging tests and treatments that do not need an MD with at least three

of doctors seeing patients

who do not require ap-

years of post-MD training to do. Second, we have a lot

pointments for things like follow-up visits.

When I was training to become a breast oncologist, I was told that for women with early-stage breast cancer, you remove the lump, give them six months of chemotherapy, and then bring them back every three months for followup. Where did that come from? Right after finishing chemotherapy, the cancer should probably be at the lowest risk for coming back. Every three months sounds like overkill to me. There are no data, no evidence that is the right time sequence, etc. We ended up with this general overkill for a lot of sequences.

**DR TOPOL:** The 2017 Association of American Medical Colleges (AAMC) report zoomed in on three things: the aging population; the aging of doctors and the fact that half of doctors are well over 50-55 vears and are retiring or burned out and are reducing their effort; and the issue about lengthy work hours and how that is just unsustainable. You underscore that the number

of medical schools in the United States has increased from 125 to 145, and the number of medical trainees has increased almost 30% in recent years. How do you square away the AAMC's assertions with your math and views?

**DR EMANUEL:** First of all, we have had an aging population for a long time now. We have learned that, yes, the population ages, and they have more chronic illness. But the best way of attacking chronic illness and managing it may not be with more doctors but rather with more chronic care coordinators who take responsibility for reaching out to patients.

When you look at the aging of the doctor population, I do think the AAMC has a point. A lot of doctors in the older generation used to work like maniacs. With my father, a 70-hour work week was normal, but the current generation does not want to work so much.

Even when you do the math under very conservative estimates of not overworking the doctor (30-minute primary care appointments, no weekend work days, no extended hours, 12 slots a day per primary care doctor), you have more than enough slots to handle the billion appointments we have every year in the outpatient setting.

**DR TOPOL:** Another metric used a lot is wait times. Since wait times have been creeping up, the idea is that we do not have enough doctors. What are your thoughts about that?

**DR EMANUEL:** Wait time is not a function of doctor supply; it is a function of how you manage doctor

time. I went around the country looking at places that provide high-quality, low-cost care, and one of the things I noticed is that they have "open-access scheduling."

At the start of the day, between 20% and 50% of the physicians' slots are open and unscheduled so that patients can walk in or call and say, "I have some free time. Can I see my primary care doctor and get my annual exam?" That management style, ironically, opens up additional free time in doctor schedules because you have fewer no-shows.

**DR TOPOL:** You have made a really good argument here that goes against almost every point in the AAMC report. Would you say that the AAMC has a conflict of interest?

**DR EMANUEL:** They do represent medical schools, and they want more of them, so they have increased authority. But a lot of medical schools, like the University of Chicago, have actually been shrinking. I think we really do need to be much more critical of their position.

It's not just medical schools but also postgraduate training—internships and residencies. Do we need all of those slots? We have a lot of slots. Those slots are not always geared toward the trainees; they are often geared toward satisfying hospital overnight coverage situations and services.

We need to rethink this. Not only do we train the doctors we graduate here, but we bring in foreign medical graduates to fill other residency slots. Is that a good use of our resources? We ought to think about overnight coverage in different ways.

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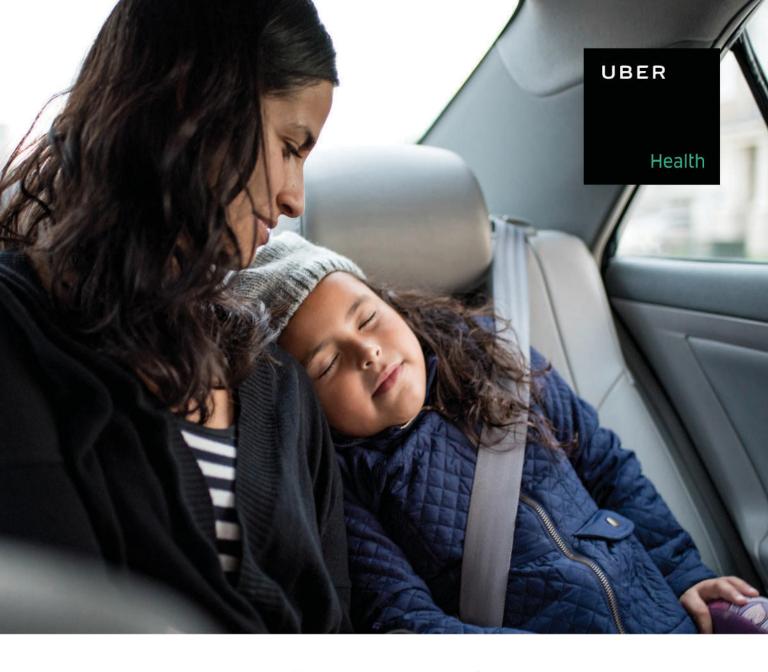
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