PHYSICIAN Risk Management

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When patients unable to pay for care that's needed, strategies decrease risk

Alternatives to costly treatments might be patient's only option

"I can't afford that test." "My insurance says I have a $2,000 deductible." "I haven't filled that prescription in months because it costs too much." How a physician responds to such statements from patients could play a role in whether he or she faces a malpractice suit if a bad outcome occurs.

"Ignoring these statements isn't a good idea," says **Anupam B. Jena**, MD, PhD, an assistant professor of health care policy and medicine at Harvard Medical School and a physician in the Department of Medicine at Massachusetts General Hospital, both in Boston.

"Good communication is the cornerstone of good patient care, and it has the extra benefit of probably lowering malpractice risk," says Jena. "Open conversations and shared decision making about these issues would therefore probably lower malpractice risk."

Stephen A. Frew, JD, vice president of risk consulting at Johnson Insurance Services in Madison, WI, and a Rockford, IL-based attorney, has seen a patient's inability to pay for care become a factor in malpractice litigation in these ways:

- The patient is unable to obtain medications or other care, and a bad outcome results.

"If not handled with the proper approach, adverse outcomes can lead to claims and litigation," says Frew.

- In a small percentage of cases, individuals might sue as a last resort, when all other options to cope with the expense appear hopeless.[1]

Frew has seen some malpractice lawsuits triggered by aggressive collection actions by a hospital or physician practice, by patients who already were dissatisfied with their care.

"This forces the patient into a perceived need to take defensive action," he says.

- A patient who lacks funds for needed medical care perceives the physician as uncaring about the patient's financial situation.

"This perception on the part of a patient

> *"Good communication is the cornerstone of good patient care ..."*

INSIDE

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or family tends to generate the most common source of litigation: anger and frustration with the system," says Frew. "The patient seeks to correct a perceived injustice."

Informed consent is issue

Physicians need to understand how economics might play into their malpractice risks, says **Dana Welle**, DO, JD, FACOG, FACS, physician risk consultant at Stanford (CA) Hospital & Clinics, "and at the heart of this issue is informed consent."

While a physician should make clinical recommendations based on the standard of care, she says, patients also need to understand the costs associated with recommended care. Once a patient understands the recommended treatment and alternatives, and costs associated with each, the patient can make an informed choice, says Welle.

"When a patient is not made aware of the costs associated with their care, it can prompt the patient to delve deeper into their clinical outcome," says Welle. "It is not uncommon for patients to re-evaluate their care once a bill for services arrives."

This situation can lead to an increase in patient complaints and a potential for a malpractice claim that, even if unsubstantiated, still needs to be investigated and defended.

"This is not to suggest a physician actually have a financial discussion during the course of a clinical intervention," Welle says. "But the physician should be aware of the mechanisms for the patient to obtain financial information."

Allow patient to decide

If a patient can't pay for care, or can pay only for limited care, this situation could lead to certain tests or procedures not being performed that could have diagnosed or treated an illness. "Failure to do so could, in theory, lead to at least a malpractice case, if not an actual payment," says Jena.

However, the opposite also can be true. "Performing more tests or procedures can also expose a physician to more liability, since it introduces the possibility of iatrogenic errors," says Jena.

Executive Summary

Physicians face legal risks when patients are unable to pay for recommended care, but risks can be lowered with shared decision-making and careful explanation of risks and benefits of alternatives.

- ✦ If a patient states he or she can't afford recommended care, the physician should consider alternative options.
- ✦ Physicians should take a patient's ability to pay into consideration.
- ✦ If less expensive and less effective alternatives are recommended, physicians should ensure patients understand the risks and benefits of choosing them.

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It's important for physicians to recognize what patients can and can't pay for, and for patients to understand the risks, benefits, alternatives, effectiveness, and costs of specific interventions, he says.

"Of course, that discussion should be documented," Jena says. "It's fine to recommend less effective treatment, but the most important thing is to allow the patient to decide what's best for them."

Not necessarily "high-risk"

Many physicians immediately will assume that patients who say they can't afford care are suddenly moved into the "high-risk" threat level for malpractice litigation, says Frew, and will assume a defensive posture.

"The latest research, however, shows that 'poor' patients are less likely to resort to litigation then their affluent counterparts," says Frew.[2]

Frew says the best approach for physician response in this situation is to assume the posture of "the concerned provider of solutions."

"While these situations may take more of the physician's time, they occur with such regularity that a standard protocol should be developed," says Frew. The protocol could give various options for patients who can't afford expensive tests, post-discharge drugs, or medical follow-up, for example.

It is understood the physician must make a living and is entitled to receive compensation, says **Leilani Kicklighter**, RN, ARM, MBA, CHSP, CPHRM, LHRM, principal of the Kicklighter Group in Tamarac, FL.

"However, to refuse to care for an established patient who cannot pay could create problems for the physician, such as abandonment, and what no doctor wants: bad publicity," she says.

4 recommendations

Kicklighter gives these recommendations:

• If the patient is hospitalized, the physician might consider involving the unit nurse manager and the finance department in the patient's case to assist the patient in obtaining coverage or other types of assistance. For example, a patient might be referred to a federal, state, or locally funded outpatient clinic.

"If the patient is in the physician's office when this comes up, hopefully the physician has assigned a member of his staff to research the agencies and facilities where the patient can be referred to explore and obtain financial support for medical care," says Kicklighter.

Refer or facilitate referral

• If the care needed is outpatient and the patient does not require hospitalization, the physician can refer or facilitate the patient's referral to a clinic.

• If the patient has an emergency medical condition, the patient should be referred to the closest emergency department.

• If a patient can't pay for medication, the physician can refer the patient to the pharmaceutical company, as some have programs to help patients in this circumstance, or any community resources that offer similar assistance.

"Documentation of discussions with the patient and family is prudent," says Kicklighter. *(See stories on common factors in claims involving patients unable to pay, below, and how physicians can respond if patients state they can't pay, p. 135.)*

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Plaintiff in these med/mal cases was unable to pay for care

Scott O'Halloran, JD, an attorney in the Tacoma, WA, office of Williams Kastner, has handled several malpractice cases involving patients who couldn't pay for care. Plaintiff attorneys have argued that a physician should be held liable for failing to prescribe a less expensive medication and also for failing to appeal an insurance company's denial of a diagnostic test.

Here are some common factors in these claims:

• Patients are unable to pay for medications prescribed by the physician.

In one case, a cardiologist prescribed an important heart medication. "It was expensive, and the patient only took it sporadically due to cost," says O'Halloran. "The cardiologist was criticized for failing to provide free samples to the patient."

In another case, a patient suffered from very high tryglicerides and high LDL cholesterol, and the patient needed a combination drug therapy including a fibrate and a statin.

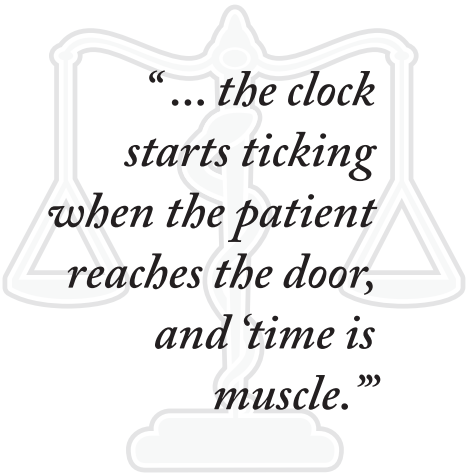
"Unfortunately, the only generic statin available on the market at the time was simvastatin which, when combined with a fibrate, was known to increase the risk of acute renal failure in some cases," says O'Halloran. The patient could afford only the generic statin and ended up developing acute renal failure.

"The physician was criticized for failing to prescribe a more expensive alternative to simvistatin," says O'Halloran. The case resulted in a verdict for the plaintiff.

"An attempt to obtain approval for the more expensive drug and documentation regarding the relative risk and increased monitoring may have made the claim more defensible," O'Halloran says.

• Imaging was ordered, but the patient failed to have it done because he or she could not or would not pay for it.

In a recent malpractice case, plaintiff attorneys made an issue of the fact that the patient's insurance company refused to pay for a patient's MRI because they thought it was not indicated. "In that case, a brain tumor would have been diagnosed in its early stages, had the MRI been done," says O'Halloran.



"... the clock starts ticking when the patient reaches the door, and 'time is muscle.'"

There was a defense verdict, but the primary care physician was criticized for failing to appeal the insurance company's denial. "Standard of care probably does not require a physician to appeal a denial, but some experts may disagree," says O'Halloran.

Some physician practices employ an assistant to advocate for low-income clients to ensure they get the medication and tests they need, he notes.

• The patient fails to follow up as directed to avoid the cost.

Paramedics urged a woman with transient heart pain to go to the ED, but the patient refused to do so because she was worried about the cost. "The woman did not want an ER bill, and she delayed going until it was too late," says O'Halloran.

Nevertheless, when she did finally come to the ED and had a bad outcome, the ED staff was criticized for not getting the patient diagnosed and into the cardiac catheterization lab for angioplasty sooner, says O'Halloran, noting that the case was settled.

"A patient's failure to come sooner may reduce the risk of a plaintiff verdict," he acknowledges. "But it won't eliminate it, because the clock starts ticking when the patient reaches the door, and 'time is muscle.'" ✦

Refusal-of-treatment forms document patient's decision

However juries expect physicians to find way to pay for needed care

If a patient states he or she can't afford recommended care, the physician can try to work with the patient to develop a plan, advises **Scott O'Halloran**, JD, an attorney in the Tacoma, WA, office of Williams Kastner.

"In general, there is usually always a way to pay for needed care," he says.

If the patient still refuses recommended treatment due to cost, the physician needs to explain the risks of failing to follow through with the recommended therapy, says O'Halloran, and clearly document the patient's decision in the chart.

Just as physicians' offices have informed consent forms, they should have refusal-of-treatment forms, says **Leilani Kicklighter**, RN, ARM, MBA, CHSP, CPHRM, LHRM, principal of the Kicklighter Group in Tamarac, FL. Document the discussion with the patient that includes the reason why the patient is refusing, the attempts the physician and staff made to overcome obstacles, risks of refusal of care, and alternatives that were discussed, Kicklighter says. This information should be documented not only in the medical record, but also on the refusal form that the patient signs and is put in the medical record, she adds.

When patients cannot afford a test, treatment, or medication, she advises that the physician or his staff work with the patient to find an alternative, appropriate test, treatment, or medication. In addition, says Kicklighter, practices can refer the patient to an agency such as "2-1-1," a national program for help for food, housing, referrals for care or other support *(For more information, go to http://211us.org)*.

"Every [physician practice] should be familiar with that phone number and the services available through that program," says Kicklighter, adding that physicians or their staff members also can refer patients to local resources available through community groups and religious organizations.

O'Halloran says that in his experience, "Juries expect that physicians, and especially hospitals, will find a way to provide needed medical therapies regardless of the patients' finances." ✦

'I'm sorry' laws are being put to the test, revealing weaknesses in legal protection

Ruling distinguishes between full and partial apologies

(Editor's Note: This is the first story in a two-part series on apology laws. This month, we report on how a recent court ruling distinguishes between apologies that express sympathy and those that acknowledge fault. Next month, we'll cover how a physician's apology could affect the outcome of a malpractice suit.)

If a physician says "I'm so sorry for what happened to you," he or she might have legal protection under a particular state's "apology" law. However, that protection might not be the case if the physician adds a statement such as, "And I apologize for giving you the wrong medication."

A March 2014 ruling by Utah's Court of Appeals has made a distinction between apologies that acknowledge that a healthcare provider was to blame for a complication or adverse outcome and apologies that merely express sympathy or explain the events causing a patient's injury.[1]

Here, a physician told the patient "I'm really sorry. There was kind of a complication. We messed up...." The portion of the conversation where the physician stated "we messed up," was interpreted by the Utah appeals court as a statement of fault that was not protected by the state's apology law.

"Nonetheless, the healthcare provider prevailed in the case for other reasons," says **Anna C. Mastroianni**, JD, MPH, a professor at the University of Washington School of Law in Seattle.

A 2010 analysis of "apology" and "disclosure" laws in 34 states and the District of Columbia found that most of the laws have major shortcomings. According to the researchers, these shortcomings could weaken the laws' impact on malpractice suits and actually discourage comprehensive disclosures and apologies.[2] "We predicted just this — that the 'I'm sorry' laws would reveal their weaknesses when put to the reality test," says Mastroianni, the study's lead author.

The March 2014 ruling reveals a disconnect between the way physicians see apologies and how lawyers and judges will interpret the laws protecting apology, says Mastroianni.

"My concern is that this case will actually end up discouraging physician apologies following medical error," she adds.

Physicians need to be aware that state laws vary on whether they protect an expression of sympathy, an explanation of what happened, and an expression of fault, advises Mastroianni. "Even if these three aspects of an apology are expressed in one sentence, the legal system may only protect the expression of sympathy and then allow the other aspects to support an injured patient's malpractice case," says Mastroianni.

The wording of some apology laws covers all statements, affirmations, gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence. However, "some states use the same wording, but with the word 'fault' deliberately removed," says **Benjamin Ho**, PhD, assistant professor of economics at Vassar College in Poughkeepsie, NY, and the study's co-author.

By clarifying the distinction between "full" and "partial" apologies, says Ho, the Utah ruling "essentially makes partial apologies less costly, making them both easier and less sincere."

The 2011 analysis, however, found no statistical difference in malpractice claims between states that that had full apology laws and states with partial apology laws.[3] "This suggests that this distinction may be too small to affect patients and doctors in their litigation decisions," says Ho.

On the other hand, a partial apology could be seen as insincere, thus increasing the distrust between patient and doctor. "One concern regarding apology laws that prompted our study is that these laws may make apologies feel even more insincere to the patient," says Ho.

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Executive Summary

A March 2014 ruling by Utah's Court of Appeals distinguishes between apologies that merely express sympathy for an adverse outcome or complication and those that acknowledge fault.

- ✦ State laws vary as to whether they protect an expression of sympathy, an explanation of what happened, or an expression of fault.
- ✦ The physician's statement "we messed up" was interpreted as a statement of fault that was not protected by the state's apology law.
- ✦ A partial apology could be seen as insincere, thus increasing the distrust between patient and doctor.

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Treating 'difficult' patient differently can backfire legally for physician

If a physician gets the impression a particular patient is likely to sue, "he or she should trust their instincts," advises **Damian D. Capozzola**, JD, of The Law Offices of Damian D. Capozzola in Los Angeles.

"If someone seems to be inclined to litigation or otherwise to be a troublemaker beyond asking the typical questions and displaying the expected emotions that patients and their family members convey in difficult situations, there is probably a basis for that perception," he says.

As with any patient, physicians should order the appropriate tests and prescribe the appropriate medicines without overtreating, says Capozzola, and document observations and conclusions thoroughly. "This does not mean that the suspected litigious patient should be treated differently than other patients, only to take extra care that the same standard of excellence aspired to with every patient is met," he says.

If physicians do treat a "difficult" patient differently from other patients, this situation can backfire legally, notes Capozzola. Differential treatment could include overprescribing or underprescribing medications, or requiring the patient to fill out burdensome forms that other patients are not required to fill out.

"A crafty plaintiff's lawyer can tie the 'different' treatment to allegations, whether legally relevant or not, that someone was treated differently and thus mistreated," he says. The attorney could argue this treatment was because of the patient's race, gender, or sexual orientation.

"Some patients have unrealistic expectations of testing or pain medications that should be ordered," says **William J. Naber**, MD, JD, CHC, an assistant professor in the Department of Emergency Medicine at University of Cincinnati.

Naber adds that in some cases, clear documentation of the interaction with the patient, and relevant medical decision making on why a test or medication was not ordered, can make a subsequent malpractice claim more defensible. "However, never write anything you would not want your mother or a jury hear you say about another person," says Naber. "Providers are professionals. Their behavior and medical record should reflect this."

EMR is powerful defense tool

If there is ever a dispute between a plaintiff and a provider on what happened, Naber says a contemporaneously recorded and professional medical record is a powerful defense tool and very persuasive to a jury.

"That way, the provider can clearly and honestly say their recollection is accurate," says Naber. "It is reflected in the medical record documented at the time of the incident, not based on a selective memory several years later."

Avoid inflammatory comments

Medical professionals, when charting an encounter with a "difficult" patient, should recognize that everything they write could someday be evidence during litigation, says Naber.

"Physicians who think they are helping themselves by loading up the medical records with unflattering descriptive adjectives about a patient will find they have done themselves a disservice when cross-examined about those potentially unprofessional terms in deposition or at trial," says Capozzola.

It is critical to keep descriptions clinical and professional, he underscores. "The safest course is to never write something down or type something out about a patient, even in jest, unless you would feel comfortable seeing it blown up on a projection screen in court and attributed to you," says Capozzola.

Phillip B. Toutant, Esq., an attorney in the Southfield, MI office of The Health Law Partners, says documentation is very important when a physician is caring for a "difficult" patient, "but only if it is done

Executive Summary

If a physician believes a particular patient is likely to sue, he or she should ensure that the care the patient receives are similar to every other patient in the practice.

✦ Plaintiff attorneys can argue that a patient was treated differently due to race, gender, or sexual orientation.
✦ Inappropriate charting on "difficult" patient behavior can cause serious problems for the physician's defense.
✦ If patients have unrealistic expectations that a particular test or medication should be ordered, documentation showing the physician's medical decision-making can be helpful.

with tact," Toutant says.

He has seen cases in which notes in the chart that document "difficult" patient behavior have caused serious problems for the physician's defense. "That being said, I think that documentation of 'problem patient' issues assists in the defense of malpractice cases," says Toutant.

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Bad outcome due to medication with black box warning? The claim is not necessarily indefensible

Document rationale for prescribing

Did a patient experience an adverse outcome from a medication with a black box warning?

Such malpractice claims "aren't necessarily indefensible," according to **Lizabeth Brott**, JD, regional vice president of risk management at ProAssurance Companies in Okemos, MI. *(See story on claim involving a medication with a black box warning, p. 139.)*

The central issue in malpractice claims involving complications arising from FDA-approved medications, including those with black box warnings, is whether the physician acted prudently within the community standard in prescribing the device or medication given the patient's history, physical condition, and all relevant laboratory and imaging data, says **Richard F. Cahill**, Esq., vice president and associate general counsel at The Doctors Company, a Napa, CA-based medical malpractice insurer.

"In evaluating the appropriate treatment course, the physician must consider whether there are any overriding circumstances that, despite the potential benefits of the product, would make the device or medication contraindicated, including any published black box warnings," says Cahill.

A physician who is supported by the prevailing community standard in the decision to prescribe a medication with a black box warning, where an appropriate informed consent was obtained from the patient "should prevail in any subsequent claim," he says.

Significant safety data

Black box warnings "emphasize significant and serious safety data for prescription drugs," says **Allen J. Vaida**, PharmD, FASHP, executive vice president of the Institute for Safe Medication Practices (ISMP).

The ISMP's National Medication Errors Reporting Program has received multiple reports of situations in which drugs were prescribed or dispensed in a way that is cautioned against in the boxed warning and resulted in serious consequences for patients. "For example, opioid-naïve patients and postoperative patients have been prescribed transdermal fentanyl patches for pain, resulting in death," says Vaida.

Brott encourages physicians to consider these practices when prescribing medications with black box warnings:

• Obtain the patient's informed consent in writing.

"When there is the potential for serious risks to occur, it's important to discuss such risks with patients," says Brott. Physicians' informed consent discussions might include an explanation of the black box warning and increased risks; the nature of the proposed treatment; the risks, potential benefits, and alternative treatment options; the rationale for the specific treatment, and the risk of failure to treat.

"Ask patients to verbally describe their understanding of your treatment recommendation to verify they understand the risks," advises Brott. "Document your conversation with the patient, and the patient's agreement, in the medical record. Include the patient's signed informed consent in the medical record."

• Document the rationale for their decision to prescribe a medication with a black box warning.

"We can always defend a well-rea-

Executive Summary

Malpractice suits involving adverse outcomes from medications with a black box warning are defensible if physicians are supported by the prevailing community standard in the decision to prescribe. To reduce risks, physicians can:

✦ Obtain written informed consent when there is the potential for serious risks.
✦ Show that effective alternatives were considered first.
✦ Document the rationale for their decision to prescribe.

soned decision. What we can't defend is a decision without support," says Brott.

Physicians might document why they thought the benefits outweighed the risks for a particular patient, or the fact that a particular risk occurred only in a small percentage of patients.

Rationale is important

It would be helpful for the defense to have an expert witness testify that most physicians would be likely to prescribe the drug in the given scenario, says Brott, but contemporaneous documentation of the physician's rationale for prescribing is also important evidence.

Prescribing a medication with a black box warning "may be appropriate in certain cases, but physicians should be prepared to explain why," she says.

Was physician negligent?

Occasionally a pharmaceutical company or the FDA will issue a medication alert reporting new data on previously unreported side effects and contra-indications.'

"Depending on the timing and nature of the alert or recall, physicians may be named as a defendant in a professional negligence suit," says Cahill.

Assuming that the physician's original decision to prescribe was appropriate, he says that the plaintiff's attorney will next determine when and how the practitioner subsequently became aware of the new data. This awareness might have occurred through direct contact by the pharmaceutical company, or the plaintiff could argue that the physician should have reasonably been aware of the information available in the medical literature.

"If the physician failed to act in a timely manner or to provide a sufficient notification to his patients involved with the medication, and physician's inadequate response proximately resulted in damage to the patient, liability may be established, and an adverse verdict may be rendered in a subsequent lawsuit," says Cahill.

SOURCES

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Cardiologist who prescribed medication with black box warning was defended successfully

A recent malpractice case involved a cardiologist who prescribed amiodarone, a drug with a black box warning, to a patient with heart palpitations.

"The drug, at that time, was commonly being used for patients with heart palpitations, but there was a black box warning indicating that it could cause loss of vision," says **Lizabeth Brott,** JD, regional vice president of risk management at ProAssurance Companies in Okemos, MI.

Within 24 hours of starting the medication, the patient reported headaches and blurred vision. "The cardiologist explained to the patient that to effectively treat her, she would need to stay on the medication for a while, and the patient was left on the medication for five weeks," says Brott.

Subsequently, the patient saw an ophthalmologist who confirmed a decrease in visual acuity. "The patient returned to the ophthalmologist four months later complaining of blurred vision which had subsequently resolved. The patient was told to return immediately if it occurred again," says Brott.

The patient returned to the ophthalmologist two months later and was referred to a retinal specialist who noted elevated pressure in both optic nerves. The patient was referred to a neurologic ophthalmologist, who diagnosed optic neuritis and recommended the patient's cardiologist switch her to another medication.

"The neurologic ophthalmologist's notes concluded the patient, 'probably experienced ischemic optic neuropathy possibly complicated by the amiodarone,'" says Brott. "So we now had documentation potentially linking the drug to the blurred vision."

Plaintiff didn't pursue claim

The patient subsequently had cataracts removed from both her eyes.

"This ultimately resulted in overall visual acuity of 20/30," says Brott.

The patient sued the cardiologist. The plaintiff's cardiology expert produced several articles that suggested there was strong circumstantial evidence linking the drug to optic nerve injury.

"The plaintiff's cardiologist expert maintained that amiodarone was an inappropriate choice, and an ophthalmologist was willing to testify that 98% of the patient's visual defects were caused by amiodarone-induced optic neuropathy," says Brott.

The black box warning indicated that amiodarone should only be administered in a controlled hospital setting and that the patient should be strictly monitored during a limited course of treatment.

"It also indicated that baseline lab work should be obtained, which did not occur in this case," says Brott. "The 'PDR' ['Physicians' Desk Reference']

also warned of possible optic neuropathy."

Despite this information, the case was dismissed prior to trial. Here are some reasons why the defense was successful:

• The defense cardiology expert witness was prepared to testify that amiodarone was appropriate to use as a first-line rhythm control agent for treatment of atrial fibrillation, given the patient's medical problems and history.

• A neuro-ophthalmologist was prepared to testify there was no causal link between the amiodarone and the optic neuritis, and that given the patient's medical history, it was likely the vision loss was associated with an ischemic event resulting in ischemic optic neuropathy.

• A National Institutes of Health researcher was prepared to testify that given the patient's age, that amiodarone was an acceptable first-line rhythm control agent for treatment of atrial fibrillation, and that age, smoking, hypertension and drinking made the plaintiff a likely candidate for structural heart problems.

"All of these factors combined ultimately led the plaintiff to decide not to pursue the case," says Brott. ✦

Successful suits against physician unlikely if device or drug is pulled from market

Plaintiffs have 'uphill argument' to hold doctors liable

Most likely, a physician will not be liable for damages a patient incurs from a medication or device that was pulled from the market, says **Mary C. DeBartolo**, JD, an attorney in the Chicago office of McGuireWoods.

Many clinics and practitioners were sued after the fungal meningitis outbreak in October 2012 as a result of the tainted compounded products provided by the New England Compounding Center in Framingham, MA.

"Although it may be unlikely that the providers will be found liable, if there is evidence that a provider was aware that the compounded products violated federal and state regulations or that the products were substandard products, then there is a possibility that a provider may be found liable," says DeBartalo.

Plaintiff has uphill battle

The plaintiff can argue that the physician should have known a medication or device was about to be pulled from the market and, therefore, the physician should not have prescribed it to the patient. "But the plaintiff would have to produce evidence supporting this argument, which may be difficult," DeBartolo says.

The plaintiff would most likely have to demonstrate that the provider should have known that the product was about to be pulled from the market and that an average provider would have known this information. "This seems like an uphill argument to make, and very much dependent on the facts and circumstances," says DeBartolo.

To prevail on such a claim at trial, a plaintiff will have to present expert opinion testimony that establishes a "standard of care" for the physician under the specific facts and circumstances of the case, says **Madelyn S. Quattrone**, Esq., senior risk management analyst at ECRI Institute, a Plymouth Meeting, PA-based organization that researches approaches to improving the safety, quality, and cost-effectiveness of patient care.

"The question is what information, if any, is a physician required to know with regard to a potential recall action of the FDA." asks Quattrone. "The reliability of information from 'secondary sources' may be called into question."

Strategy needed

Whether a physician would be held liable depends on the plaintiff's theory of liability as applied to the unique facts and circumstances of the case, whether the manufacturer is also a defendant in the lawsuit, and the theory of liability against the manufacturer, says Quattrone.

ECRI Institute is aware of at least one case in which recall information about an affected device did not reach all areas of the organization where the device was used.

"Organizations must therefore, have comprehensive risk management strategies to identify recalled medical devices and medications and to safe-

Executive Summary

Successful malpractice suits against physicians for complications arising from medications or devices that were pulled from the market are unlikely.

✦ A provider might be found liable if there is evidence that a provider was aware that products violated federal and state regulations.
✦ The plaintiff generally has to demonstrate that an average provider would have known the product was about to be pulled from the market.
✦ Physician practices should create an inventory of equipment and devices.

guard against using the affected medical device or medication," says Quattrone. She gives these recommendations:

• Physician practices should create an inventory of equipment and devices.

For each device, the practice should list the manufacturer, model, and serial number; the software version if applicable; acquisition and warranty expiration dates; the maintenance provider and contract dates, if applicable; and contact information for requesting maintenance.

"The practice should also maintain an inventory of all vaccines, medications, and biologics maintained within the practice," says Quattrone. "Document information such as drug strength, drug lot numbers, and expiration dates."

• The practice should have a process for receiving and communicating drug hazard and recall information regarding any medications, vaccines, and biologics used within the practice.

"When a physician practice receives a recall or hazard notice from a manufacturer or distributor, it becomes responsible for taking appropriate corrective action," Quattrone explains.

If the practice fails to take appropriate action after receiving such notice and a patient is injured by the defective device or affected medication, the physician might be found negligent.

"It may also bear legal responsibility for improper modifications made to a medical device as a result of a recall notice," says Quattrone.

SOURCES

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Court says warrant needed for blood alcohol test — Non-compliant physicians could face battery claim

Physicians caught in the middle between patient, law enforcement

In the April 2013 case of "Missouri v. McNeely," the Supreme Court ruled that police must generally obtain a warrant before subjecting a drunken-driving suspect to a blood test. This ruling has significant implications for physicians' malpractice risks.

"If a physician draws blood from a person without consent or a warrant for the purpose of conducting a DUI blood alcohol test, it exposes the physician to a battery claim," says **Douglas F. Ciolek**, Esq., an attorney at Reiseman, Rosenberg, Jacobs & Heller in Morris Plains, NJ.

Moreover, absent consent or a warrant, a physician-employee of a public hospital can be liable under federal and state civil rights statutes. "Furthermore, even a physician associated with a private hospital can sometimes be deemed a public actor," Ciolek says. This situation exposes the physician to a potential civil rights claim when the physician "acted together with or obtained significant aid from state officials," or was a "willful participant in joint activity with the state or its agents."

In addition, if the phlebotomy causes an additional injury such as an infection or nerve damage, a malpractice claim always can be asserted irrespective of consent or any warrant. "Consent or a warrant does not immunize a physician from performing the phlebotomy in a negligent manner," Ciolek adds.

Warrant "rule, not exception"

Physicians are often "caught in the middle" of wanting to cooperate with law enforcement requests and caring for the patient, says **John Tafuri**, MD, FAAEM, regional director of TeamHealth Cleveland (OH) Clinic and chief of staff at Fairview Hospital in Cleveland. "When you cloud those two, there is the potential to get into trouble," Tafuri says.

Plaintiff attorneys likely will argue that physicians should be familiar with the court ruling, Ciolek says. "Physicians need to be aware that a warrant is now the rule and not the exception," he says. "There should be no excuse by the physician that 'I was just doing what was asked of me.'"

The Supreme Court ruling tends to increase legal risks for physicians if they forcibly perform a blood draw without

Executive Summary

A recent U.S. Supreme Court ruling that police generally must obtain a warrant before subjecting a drunken-driving suspect to a blood alcohol test has important malpractice implications for physicians.

✦ Physicians have exposure to a battery claim if they conduct a blood alcohol test without consent or a warrant.

✦ Consent or a warrant does not immunize a physician from liability for performing the phlebotomy in a negligent manner.

✦ Evidence that the physician was acting in the patient's best interest can make claims including assault allegations more defensible.

a warrant, says Tafuri, "and physicians may not be cognizant of the legal requirements of the ruling."

If a patient refuses a blood alcohol draw and is forcibly restrained and the blood is drawn without a court order, the physician potentially could face an assault allegation. This allegation is difficult to prove, however, particularly when the physicians can show they were acting in the best interest of the patient.

"If someone is not cooperative, even if they are not refusing, they can make all sorts of spurious allegations that the blood was illegally or negligently drawn," says Tafuri.

If the physician can show he or she was drawing the patient's blood to rule out a serious medical condition due to a change in the patient's mental status, for example, this situation makes such claims more defensible, he says.

Risk-reducing approaches

Physicians should consider these approaches to protect themselves legally, Ciolek advises:

• Physicians should be familiar with the hospital's policy that addresses police-requested phlebotomies.

"If there isn't one at their hospital, the issue should be raised immediately," Ciolek says. "Preferably, hospital policy should require a search warrant before even considering such a request."

A concise and thorough policy that was vetted and approved by the hospital's legal department will provide the proof and the explanation of why the physician did or did not draw a suspect's blood, he adds.

Most states have enacted some degree of statutory immunity for medical providers who draw blood at law enforcement's request, but this immunity varies from state to state. "This is something that should be reviewed in advance by the hospital's attorneys, and incorporated into hospital policy and made available to all physicians," Ciolek says.

• Physicians should check with insurance brokers to confirm that coverage exists for battery claims.

"Everyone knows that a typical malpractice claim alleges negligence," Ciolek says. "However, a battery claim may cause a physician's insurer to disclaim coverage, because intentional acts are generally not covered under a malpractice policy."

A physician should determine if the hospital and/or law enforcement agency will provide indemnification for all claims arising out of such an event, adds Ciolek.

• Physicians should record everything relevant to the event.

"Include who requested the phlebotomy, if consent was given, the circumstances surrounding the phlebotomy, and the need for same," Ciolek says.

SOURCES

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CME OBJECTIVES

After reading *Physician Risk Management*, the participant will be able to:

- describe the legal, clinical, financial, and managerial issues pertinent to physician risk management;
- explain the impact of risk management issues on patients, physicians, legal counsel, and management;
- identify solutions to risk management problems for physicians, administrators, risk managers, and insurers to use in overcoming the challenges they face in daily practice.

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To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
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5. Once the completed evaluation is received, a credit letter will be emailed to you instantly. ✦

CME Questions

1. Which is true regarding physicians' legal risks if patients are unable to pay for care, according to Anupam B. Jena, MD, PhD?

A. If a patient states he or she can't afford recommended care, the physician should never offer less costly alternatives.

B. Physicians have a legal obligation never to consider cost as a factor in their medical decision-making.

C. If cheaper alternatives are recommended, physicians should ensure patients understand the associated risks and benefits.

D. Refusal-of-treatment forms should never be used if patients state they are unable to pay for care.

2. Which is true regarding legal protection under apology laws, according to Anna C. Mastroianni, JD, MPH?

A. There is no legal distinction between apologies that acknowledge that a healthcare provider was to blame for an adverse outcome and apologies that merely express sympathy.

B. No states currently have apology laws that protect a physician's explanation of the events causing a patient's injury.

C. Physicians need to be aware that state laws vary on whether they protect an expression of sympathy, an explanation of what happened, and an expression of fault.

D. All apology laws specifically protect a provider's expression of fault.

3. Which is true regarding lawsuits involving adverse outcomes from medications with a black box warning, according to Richard F. Cahill, Esq.?

A. Such claims generally are defensible if physicians are supported by the prevailing community standard in the decision to prescribe.

B. It is not advisable for physicians to obtain the patient's written informed consent before prescribing.

C. Evidence that the physician considered effective alternatives always will complicate the defense of the claim.

D. Physicians should not specify their rationale for the decision to prescribe a drug with a black box warning.

4. Which is true regarding liability risks of devices or drugs that were pulled from the market, according to Mary C. DeBartolo, JD?

A. Successful malpractice suits against physicians for complications arising from medications or devices that were pulled from the market are unlikely.

B. A provider cannot be found liable even if there is evidence that a provider was aware that products violated federal and state regulations.

C. The plaintiff never has any legal obligation to demonstrate that an average provider would have known the product was about to be pulled from the market.

D. A physician practice has no legal responsibility to take appropriate corrective action after receiving a recall or hazard notice from a manufacturer or distributor.

Physician Legal Review & Commentary

Expert analysis of recent lawsuits and their impact on physician risk management

Surgery and bariatric program problems result in $10.6 million verdict

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News: The patient, a 39-year-old woman, underwent laparoscopic bypass surgery, a surgery used to help with weight loss, in December 2009. There were immediate complications, as the patient suffered from a fever and a tachycardic heart rate shortly after the initial surgery. The patient continued to suffer in considerable pain, but her physician failed to respond promptly. A second, exploratory surgery was performed, and the physician ultimately did discover and attempted to repair an intra-abdominal gastric leak. By January, she was discharged despite suffering from fever and high blood pressure. Five days later, the patient died. The patient's husband brought suit and alleged that the physician had been negligent in the two surgeries and follow-up care. The physician and hospital denied any wrongdoing. The jury found the physician and hospital liable and awarded $10.6 million in damages.

Background: In this matter, the patient was a 39-year-old woman who underwent laparoscopic gastric bypass surgery, a common procedure to help with weight loss. The initial surgery took place in December 2009, and problems occurred quickly as a result. The patient developed a fever and a tachycardic heart rate. The following day, the patient suffered from considerable abdominal pain. Tests revealed that the patient had abnormal activity, which necessitated her move to the intensive care unit a day later. Hospital nurses were primarily taking care of the patient at this time, as the physician did not respond to the patient's worsening condition. The patient displayed signs of an infection, which, based on the bypass surgery, could reveal a gastric leak.

Hospital nurses had concerns about the physician's treatment of the patient ...

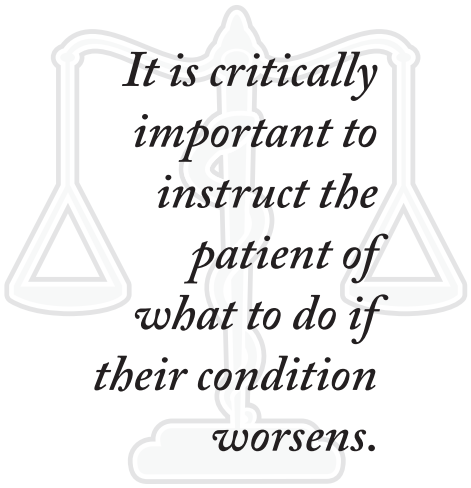
Once the physician did respond to the patient's condition, he performed a second surgery, and he discovered an intra-abdominal gastric leak. This second surgery attempted to repair the gastric leak, but the patient's condition did not considerably improve. During her recovery from this second surgery, the patient was placed on a breathing vent, and her blood pressure was recorded at 196/93 despite medication attempting to curb this high blood pressure. Hospital nurses had concerns about the physician's treatment of the patient, which was subsequently revealed at trial through the nurses' notes. Nevertheless, the physician discharged the patient, who at the time still suffered from a fever and high blood pressure. The patient's husband attempted to contact the physician and sought a wound vacuum-assisted closure (VAC) to help heal his wife's wounds, but these attempts were futile. The patient died five days after being discharged from the hospital, and a later autopsy revealed gruesome details about the serious damage caused to the patient's intestines as a result of her infection.

Financial Disclosure: Co-Authors **Damian D. Capozzola**, **Jamie Terrence**, **Tim Laquer** and Executive Editor **Joy Dickinson** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

The patient's husband brought suit and alleged that the physician's treatment of his wife was negligent in three instances: the initial surgery, the second surgery, and her follow-up care after both surgeries. The hospital was named as well, based on its failure to properly oversee the bariatric program and failure to properly review the physician's initial procedures during the inception of the program. Evidence during the trial revealed that the hospital's program suffered from high complication rates: 28-31% of patients that this physician operated on suffered reportable complications, and four patients, out of nearly 150, died due to serious complications. According to studies, complication rates from laparoscopic bariatric surgery are about 7%, while mortality rates vary from 0% to 0.11%. One expert witness, another bariatric surgeon, testified that his mortality rate was two patients out of more than 2,000. The defendants argued that the patient failed to follow her physician's post-surgery instructions, which would have required her to return to the hospital and seek medical attention, the day before she died. While awarding $10.6 million in damages, the jury found both defendants liable. The hospital was 60% at fault, and the physician was 40% at fault.

What this means to you: This case illustrates the need to properly follow-up and keep an eye on patients, especially those fresh out of surgery. Physicians have a responsibility to their patients, not only during surgery, but before and after as well. One major issue in this case dealt with the physician's post-surgery instructions and whether they were adequate and implemented. Physicians should be careful about discharging post-surgery patients with questionable vitals, such as the patient here who suffered from a fever and high blood pressure despite attempted treatment. Discharging a patient early might give rise to liability if a reasonable physician, given the same circumstances, would have kept the patient for continued observation or treatment. A physician's liability does not end merely because the patient has left the physician's presence.

Patients are rarely physicians themselves, and most often they don't know what needs to be done to continue on their treatment once discharged from a hospital or physician's care. Giving complete and adequate instructions to a patient before discharging is thus critical to treatment being successful. It is critically important to instruct the patient of what to do if their condition worsens. Ultimately, it is the physician's decision and responsibility to treat the patient, and that includes informing the patient about how to take care of himself or herself after discharge.



Physicians and hospitals can work together to develop a post-discharge plan for patients. They can create pre-printed forms with information for patients to take home with them to make this process easier for physicians and nurses to completely inform patients properly. These pre-printed forms can have standard sections that will be discussed and completed with specific information pertaining to an individual patient's needs. The focus of this information is to ensure that patients are fully informed about what they need to do after they leave the hospital to prevent readmission. Patients need to know about possible complications: what the signs and symptoms are including minor and major complications, how to deal with minor complications on their own or with the help of a caregiver, who to contact to ask questions, and what to do if more serious complications arise, which often means seeking emergency medical assistance. The case here reveals what might happen when patients don't understand this information: the patient and physician had different understandings about the seriousness of the patient's complications and when hospital readmission was required.

In addition to discussing potential complications, physicians should talk about medications. If a patient was taking medications before admission, these medications might no longer be necessary and might even be detrimental to the patient's health; however, the patient will not know this information without guidance. When discussing medications, this discussion should not be limited to only prescription medications. Patients might not be aware that over-the-counter medications, herbal medications, vitamins, and supplements might conflict with prescription medications, so physicians should discuss all of these types of medication and specifically ask patients whether they are taking any of these types. Any new medications that are prescribed as a result of treatment must be discussed as well. Patients need to know about proper dosages, when and how often to take (morning or evening, twice or thrice daily), and how to take the medication (with or without food or water). For patients with multiple medications, physicians might recommend that patients keep a written list of the medications. Such a list also will aid physicians during follow-up appointments, and they can update this list with the patient present.

Patients might have activity or dietary restrictions as well, depending on their condition and treatment. Many of these restrictions might seem like common sense, but providers still should have a frank discussion with patients about what they can and can-

not do, temporarily and permanently. Patients with broken ankles will be aware that they should not be walking immediately, but will not necessarily know when they are able to begin putting weight on it, begin exercising, begin running, etc. Physicians must go over these restrictions to ensure that patients do not overly exert themselves and risk worsening an injury. Likewise, dietary restrictions might be incredibly important to a patient's recovery. Based on the condition, patients might severely suffer if they eat specific types of food (fatty food, spicy food), smoke, or consume alcohol. Again, many of these restrictions often are common sense requirements that patients might know about, but physicians should expressly go over these requirements to make sure patients know the specifics and, more importantly, why these restrictions are in place. Follow-up appointments should include review of any activity or dietary restrictions, a discussion of how the patient is doing with these restrictions, and a review of any changes necessary, especially for temporary restrictions.

Preventing infections is of the utmost importance for recovering patients, particularly those who had surgery. Patients can be at increased risk for infection and illness until they are fully recovered. Physicians should inform patients of this increased risk, along with steps to take to affirmatively reduce the risk of infection and illness. General advice might include telling patients to avoid others who are sick and to make sure they receive enough sleep, which is extremely important to recovery. Proper hygiene, principally washing of hands, is important as well, to prevent external causes of infection. Surgery patients require additional special instructions on how to properly care for and keep their surgical sites clean. Providers should inform patients how to properly clean and dress wounds. They should tell patients how to use proper sterile supplies, a sample of which can be provided to the patient at the time of discharge. If the patient cannot care for himself, and a family member or friend will be caring for the patient, this person should be brought in to these discussions, because that person might be significantly responsible for assisting the patient with their recovery.

Finally, this case also illustrates the importance of competent and dedicated peer review processes. Lack of hospital oversight concerning this physician with a poor track record compared to his peers is likely why the hospital paid such a large portion of the settlement. In most institutions, active peer review bodies hold their doctors to high standards and take aggressive action against outliers. Physicians should be aware of the hospital's requirements to monitor performance and how they respond to deviations by limiting or removing credentialing privileges, and hospitals should work with counsel and risk managers to be sure appropriate peer review processes are in place. Nurses also of course have their own licenses and reputations to protect. In addition to clearly documenting their observations and actions in charts, they also need to be instructed to follow protocols established by the hospital that will allow them to express themselves if they see a course of treatment that concerns them. These expressions could include reporting to their supervisor within the nursing department and/or reporting to a dedicated person within administration whose job duties include receiving such concerns.

Reference

Circuit Court of Pulaski County, KY. Case No. 10-CI-01363. March 25, 2014. ✦

Delayed treatment of cancerous ulcer leads to $1.1 million verdict from jury

News: The patient, an elderly woman in her 70s, sought treatment in October 2007 for a plantar ulcer on her left foot. A physician at a hospital proceeded to treat her numerous times over 10 months, including treatment with bone scans, antibiotics, wound cultures, and debridements. The patient additionally sought treatment at a wound center and second physician, but the ulcer continued to grow despite these treatment efforts. Eventually a third physician biopsied the ulcer, which showed verrucous carcinoma. Ultimately, in January 2009, the patient underwent partial amputation of her foot. The patient brought suit and claimed that the first two physicians, hospital, and wound treatment center failed to diagnose her ulcer and perform the proper tests. The defendants asserted that their treatment, based on earlier biopsies, was appropriate. The jury awarded $1.1 million in damages against the initial physician.

Background: In this matter, the patient was an elderly woman in her 70s, who had a past medical history consisting of diabetes, hypertension, congestive heart failure, coronary artery disease, and blood clots. She went to a hospital in October 2007 and sought treatment for a plantar ulcer on her left foot. An initial physician began treatment that included bone scans, antibiotics, wound cultures, and debridements, and lasted over 10 months. This physician believed that the ulcer was consistent with a diabetic ulcer given the wound and the patient's history of uncontrolled Type II diabetes. When

these treatments proved to be ineffective, she went to the hospital's wound center, but the ulcer continued to grow.

In July 2008, the ulcer was determined to be necrotic, with moderate damage and an odor. A second physician, associated with the same hospital, took over treatment and saw the patient numerous times over six months. This physician recommended additional debridements and performed hyperbaric oxygen therapy at the hospital's wound center. When the ulcer began to change appearance, the physician ordered a biopsy that was reviewed multiple times. The first review claimed the biopsy did not show cancer, while the second review claimed the biopsy showed verrucous carcinoma, a type of squamous cell carcinoma. The patient consulted a third physician, associated with a different hospital, who biopsied the ulcer and found well-differentiated squamous cell carcinoma. In January 2009, the patient underwent a transmetatarsal amputation and subsequent skin graft. The patient also claimed that she continued to suffer from infected wounds, abscesses, and osteomyelitis, and that she will need future medical operations, including a metatarsectomy, as a result of the physician's untimely treatment.

The patient brought suit against the first two physicians and their associated hospital and wound treatment center. The suit argued that their delayed diagnosis of the cancerous nature of the ulcer led to invasive and metastatic skin cancer. In addition to the physical injuries, the patient maintained that her life expectancy had lowered and she had increased chance of reoccurrence, based on the physicians' negligence. The physicians offered multiple defenses, including that their treatment was appropriate and partially successful given the current nature of the ulcer that worsened with time despite their efforts, and that the patient would have required the amputation even if the diagnosis was made at an earlier time. The hospital claimed that the patient's ulcer was consistent with a slow-healing diabetic ulcer in an elderly patient, particularly given this patient's substantial past medical history. The jury found the first physician liable. However, the jury found the second physician, who settled out of the case during the trial, and the hospital not liable: the court allowed the jury to assign liability to anyone responsible for the injury based on the respective degrees of fault, even for individuals who have settled out of the case. This is an inherent risk involved with settlements, as an assigned share of fault from a jury verdict might exceed a settlement amount. It awarded the patient $350,000 in past medical expenses and $750,000 in non-economic damages.

What this means to you: The primary issue in this case dealt with whether the physicians failed to timely diagnose the patient's condition. An initial physician, charged with the responsibility of making a diagnosis, might be liable for medical malpractice if his actions fall below the standard of care of what a reasonable physician would do in similar circumstances. If the physician improperly diagnoses a condition, while a reasonable physician presented with the same or similar facts and symptoms would diagnose that condition correctly, this situation constitutes malpractice. The physician in this case created a treatment plan that was based heavily upon the patient's past medical history. Her uncontrolled Type II diabetes, he posited, was the cause of the ulcer, as the characteristics of this ulcer were consistent with a diabetic ulcer.

Looking to a patient's past medical history is an essential and necessary part of any physician's investigation into the cause and circumstances surrounding a patient's condition. A particular patient might have reoccurring medical issues, or past conditions that might have consequences to the patient's health later in life. These are valid, important concerns, and reasonable physicians are likely to consider them when consulting a patient and creating a plan of treatment. However, there can be a danger in relying solely upon this medical history: physicians should be cautious not to let the medical history distract them from objectively evaluating a patient's symptoms to fully diagnose a condition. Medical histories are but one part of the complete picture, and focusing too narrowly on a patient's particular history might cloud judgment and prevent a physician from looking to alternatives that might be equally possible causes for the condition. In this case, the initial physician likely relied too heavily on the patient's diabetes; were it not for that reliance, he might have considered the ulcer to be caused by something else. These decisions are difficult to make, but physicians are best served by being fully informed, taking medical histories into account, but not relying too substantially on any single piece of evidence. Again, the standard is "What would a reasonable physician do given the same or similar circumstances?" Thus, when evaluating what to do given relevant medical history, this question should be considered. Reasonable physicians definitely consider medical histories when diagnosing patients, but they must be careful to not give them too much deference — considering the situation as a whole will help protect physicians from liability based on a failure to properly diagnose a condition.

Reference

Court of Common Pleas, PA.Case No. 101103488.March 5, 2014. ✦