## Health Law: Quality & Liability

Professor Thaddeus M. Pope

Reading Packet for Week 8 (Fall 2018)

## **Weekly Summary**

In this class session, we are moving from informed consent to the more paradigmatic type of medical malpractice claim. We first get a sense of the size and scope of medical errors in the United States. We then turn to start examining the first element of a medical malpractice claim: "duty" or the "standard of care" against which the defendant is measured. Since the empirical background material is direct and self-explanatory, we will focus most of the lecture and discussion time on discussing the appellate cases.

We begin with the duty element (the standard of care). The standard of care is not singular and unitary. First, the standard of care against which defendants are measured may itself substantively vary from jurisdiction to jurisdiction. As we will see, there are different ways to establish the standard of care. Second, even if the standard of care itself does not vary, the way in which it must be established - as a matter of evidence - does vary from jurisdiction to jurisdiction.

Across the country, there are four different geographic variations. You might think of these as spreading out in concentric circles. First, the smallest circle represents the locality standard. The defendant is measured against the reasonable physician in the very locality where the defendant practices. While this used to be common in the United States, today, only Idaho has this rule. Second, in Arizona, Washington, and Virginia, the defendant is measured against the reasonable physician in that defendant's state. Third, in around 20 states, the defendant is measured against the reasonable physician in a locality like the defendant's (in terms of population and health care resources, no matter where that locality is situated). Finally, on the majority standard followed in more than 25 states, the defendant is measured against the reasonable physician in the United States.

In addition to geography, there are three other types of variations on the standard of care. Specifically, we will examine the school of thought (minority standard of care). While far less prevalent, we will also briefly examine two other ways in which the standard of care is established: (1) judicially, by the court, and (2) through clinical practice guidelines.

In sum, this week, we focus on establishing the standard of care (the duty element in tort based medical malpractice). Next week, we turn to causation and damages. The week after that, we will look at defenses and alternative theories of liability.

### Reading

All the following materials are collected into a single PDF document:

- Consumers Union, U.S. Senate Testimony (July 2014) (3 pages)
- Locke v. Pachtman (Mich. 1994) (standard of care) (11 pages)
- Hall v. Hilbun (Miss. 1985) (geography) (20 pages)
- Pa. Civil Jury Instructions 11.04 (school of thought) (2 pages)
- Helling v. Carey (Wash. 1974) (judicial) (3 pages)
- Mehlman, J. L Med. Ethics (2012) (CPG) (10 pages)

## **Objectives**

By the end of this week, you will be able to:

- Appreciate the scope and nature of medical error in the United States 4.1).
- Analyze and apply all four elements of a medical malpractice cause of action (duty, breach, causation, and damages) (4.2).
- Distinguish four geographic variations in how the standard of care (duty) is established (4.3).
- Analyze and apply legal principles concerning how the standard of care is established both judicially and through clinical practice guidelines (4.4).
- Analyze and apply legal principles concerning how a defendant can establish a school of thought (an alternative minority standard of care) (4.5).
- Analyze and apply legal principles concerning the qualification of expert witnesses (4.6).



# Testimony of Consumers Union U.S. Senate Committee on Health, Education, Labor and Pensions Subcommittee on Primary Health and Aging More Than 1,000 Preventable Deaths a Day Is Too Many: The Need to Improve Patient Safety July 17, 2014

Consumers Union, the policy and advocacy division of Consumer Reports, appreciates the opportunity to speak to the Subcommittee on Primary Health and Aging about an urgent health care crisis – medical errors and health care-acquired infections that kill as many as 440,000 people<sup>1</sup> and harm an estimated 8.5 million<sup>2</sup> every year in this country.

The impact on patients varies – from minor harm that is addressed quickly to permanent disability to years of recovery to death. People who are harmed lose their jobs, their homes, their health insurance. Many go bankrupt trying to pay the medical bills that they would not have had if they had not been harmed by a health care provider. These are the very real consequences of the failure to take action to address the problem of medical errors. They are our sisters and brothers, parents, and children. They have been betrayed by the system in which they placed their trust. Not because we expect perfection from nurses and doctors, but because we trust that they will use the best knowledge, diligent adherence to the best practices, pay attention to what we tell them and ask of them, understand that when we pay for their services we expect it will include doing all they can to keep us safe from harm, and when they make a mistake they will realize it, admit it, and correct it.

Since 2003, Consumers Union's Safe Patient Project has conducted a national campaign to eliminate hospital acquired infections and medical errors. A major strategy for reaching this goal is to improve public transparency about these mostly preventable events. We developed model legislation and initiated debates in nearly every state on whether hospitals should disclose their infection rates. Thirty—one states passed laws based on our hospital infection model before a federal program required such reporting for most U.S. hospitals. Public disclosure is a critical element to preventing these events from happening — it informs people about health care outcomes and motivates health care providers to do more to prevent errors.

Our work includes organizing patients and their families who have been harmed by medical care and who are working to improve the health care system to prevent harm from happening to others – in their communities and nationally. Many of them sent letters to their Congressional members last week urging them to create a National Patient Safety Board and to step up efforts to address this national crisis.

We acknowledge that many individuals, hospitals and other health care institutions are working to eliminate medical errors. Their work and progress is often the subject of Congressional hearings. But today's hearing, highlighting this national tragedy, is a call to action for a very big problem –millions of Americans are at risk for death and serious injury but the response by our leaders fails to match the scope of this epidemic.

Consider this headline: "House to push for answers on why GM failed to recall cars despite

knowledge of flaws ultimately linked to 13 deaths." The CDC home page this week highlighted salmonella infections from sprouted chia powder and pet bearded dragons and ecoli from raw clover sprouts – but nothing on infection outbreaks in US hospitals. The VA faces significant actions for delays in care, but is anyone asking about medical errors that occur at the VA and put soldiers in harms way? Diabetes kills nearly 70,000 people each year and there is a significant emphasis in our health care system to eradicate this disease. But what about the third leading cause of death? Where are the programs reaching out to help patients who are suffering from medical errors? Where is the demand for accountability of the deaths caused by preventable hospital-acquired infections?

#### MEDICAL ERRORS: THE THIRD LEADING CAUSE OF DEATH IN THE U.S.

Many names are given to medical errors and some, like "mishaps" and "misadventures" are offensive to the patients affected. The most frequently used list of medical errors was developed by the National Quality Forum (NQF). These are commonly referred to as "never events" but officially named "serious reportable events." The never events name was appropriate because these are things that should never be happening to patients in hospitals. The list includes surgical errors (such as surgery on the wrong patient, the wrong body part or leaving a foreign object in the body), care management (such as medication errors, blood errors, maternal or infant deaths during normal deliveries, serious bed sores), product or device related events (such as contaminated drugs, death due to intravascular air embolism in the use of an IV), environmental events (such as electrical burns, falls, electric shocks), and criminal and patient protection issues (such as abduction of a patient, sexual assault of a patient, suicide).

In 2011, Consumer Reports polled Americans about patient safety and asked them the terms they would use to describe these events. Medical errors and medical mistakes topped the list (48% combined). "Adverse events," a term commonly used by professionals was barely recognized (4%). How we refer to these events is critical to raising public and professional awareness. Using understandable terms like hospital-acquired infections rather than "nosocomial infections" is a small but critical step towards creating a culture focused on eliminating them.

While medical harm spans all providers – hospitals, doctors, dialysis centers, nursing homes and outpatient surgical centers – most of what we know is limited to what happens in hospitals. And what we know about hospitals is a very small part of the comprehensive problem.

More than ten years ago, the Institute of Medicine (IOM) estimated that annually 98,000 patients lost their lives due to medical harm.<sup>3</sup> Even then it was contradicted by CDC data that estimated 88,000 deaths from infections alone.<sup>4</sup> Using 2002 data, CDC updated their estimate to 99,000 deaths from hospital-acquired infections.<sup>5</sup> And the agency's 2014 prevalence estimate, based on a 2011 study was 722,000 infections in 648,000 patients and 75,000 deaths. This reflected a change in the incident rate from 5% to 4% of hospital patients or on any given day, 1 in every 25 patients will get an infection.6 Clearly this is very slow progress that cries out for more attention. CDC's media statement said, "Although there has been some progress, today and every day, more than 200 Americans with healthcare-associated infections will die during their hospital stay."

Further, antibiotic resistant infections are reaching epidemic proportions, creating another crisis

in the treatment of infections that occur. Even if there were many drug developers working on new antibiotics, the scientists cannot keep up with the bugs. By the time new antibiotics are on the market, resistances to them are forming. We cannot research our way out of this problem. The only way out is rigorous infection prevention and aggressive antibiotic stewardship programs throughout the country.

When it comes to tracking medical errors, we don't really know how many hospital patients are harmed because there is no national effort to collect this information or to make it public. But three landmark studies in 2010 and 2011 gave us some solid estimates of how often these errors and infections happen.

The studies rocked the confidence of experts in the field who assumed piecemeal efforts to prevent medical harm were having an overall effect on improving patient safety. All of these studies looked at all harm – from minor to major – and included both errors and infections. All emphasized the need for the system to focus on a broader array of adverse events than the National Quality Forum list of serious adverse events. All used techniques that avoided the underreporting problems common to hospital self-reporting and misleading billing data.

- <u>US Health and Human Services Office of Inspector General (OIG)</u> based its study on Medicare data and found that 27% of Medicare patients hospitalized in October 2008 were harmed from medical care. One in seven of them endured long-term and serious harm from hospital care (defined as events resulting in prolonged hospitalization, permanent disability, life-sustaining intervention, or death).<sup>7</sup> The OIG estimated that 44 percent of the harm identified was preventable.
- New England Journal of Medicine (NEJM) study revealed similar findings one in four hospital patients are harmed.<sup>8</sup> This study was done in North Carolina where there had been a high level of engagement in efforts to improve patient safety during the six years covered by the study. Despite this work, the surprising findings showed little evidence that harm had decreased substantially over that 6-year period. At the time, no public reporting of infections or errors was required of North Carolina hospitals. Without information about medical harm, the public cannot hold these hospitals accountable for their errors. The NEJM study found that 63% of these events were preventable and made the important point that "preventability" changes over time as new ways to keep patients safe are tried and measured.
- Health Affairs study using the Institute for Healthcare Improvement's global trigger tool<sup>9</sup> found that one in three hospital patients are harmed.<sup>10</sup> The study compared three methods for detecting adverse events in patients hospitalized in three large tertiary care centers, all teaching hospitals with well established patient safety programs, and found the most common methods used to track patient safety in the U.S. self reporting and pulling information from administrative billing documents missed 90% of adverse events.

A 2013 study, "A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care," translated existing research into a reliable estimate of how many patients die from medical errors each year. Based largely on the findings cited above, the study estimated that the premature deaths of more than 400,000 patients each year was associated with preventable medical errors. When undetected diagnostic errors were added to that number, the study estimated up to 440,000 patients are harmed each year. These new estimates established medical harm as the third leading cause of death in the US.

521 N.W.2d 786

446 Mich. 216, 521 N.W.2d 786, 42 A.L.R.5th 743

(Cite as: 446 Mich. 216, 521 N.W.2d 786)

Supreme Court of Michigan. Danny LOCKE and Shirley M. Locke, Plaintiffs-Appellants,

v.

Judith A. PACHTMAN, M.D. and James A. Roberts, M.D., Defendants-Appellees. Docket No. 96046. Calendar No. 5, March Term, 1994.

> Argued March 8, 1994. Decided Aug. 23, 1994.

Patient brought medical malpractice action against surgeon and attending physician. The Circuit Court, Washtenaw County, Henry T. Conlin, J., granted physicians' motion for directed verdict. The Court of Appeals affirmed and leave to appeal was granted. The Supreme Court, Mallett, J., held that: (1) expert's testimony was insufficient to make prima facie showing of relevant standard of care; (2) surgeon's alleged statements that "I knew the needle was too small when I used it" and that patient's injuries were her fault were insufficient to establish standard of care and breach of that standard; and (3) patient did not state prima facie case of medical malpractice on theory of res ipsa loquitur.

Affirmed.

Levin, J., dissented and filed opinion.

West Headnotes

#### [1] Health 198H 🗲 611

198H Health

198HV Malpractice, Negligence, or Breach of Duty

198HV(B) Duties and Liabilities in General 198Hk611 k. Elements of Malpractice or Negligence in General. Most Cited Cases

(Formerly 299k18.12 Physicians and Surgeons) Proof of medical malpractice claim requires demon**OPINION** 

MALLETT, Justice.

In this medical malpractice action, the trial judge granted defendants' motion for a directed verdict at the close of the plaintiff's proofs. The Court of Appeals affirmed, finding that plaintiff had failed to make a prima facie showing of the standard of care related to defendants' allegedly negligent conduct.

We affirm.

Ι

On August 5, 1981, plaintiff Shirley Locke underwent a vaginal hysterectomy with entocele and rectocele repair at the University of Michigan Hospital. The procedure was performed by defendant, Dr. Judith Pachtman, then a fourth-year resident in gynecology. Codefendant, Dr. James Roberts, was the \*\*788 attending physician and was present for most of the surgery.

FN1. As explained at trial, an entocele is an out-pouching or hernia of the peritoneal cavity where the bowel protrudes into the area between the vagina and the rectum. A rectocele is a hernial protrusion of the rectum through the posterior vaginal wall.

FN2. At trial, Dr. Roberts explained that he was the senior medical officer involved in the procedure. However, he also stated that, as attending physician, his role was to act as assistant and consultant to Dr. Pachtman, who actually performed the surgery.

Dr. Pachtman essentially agreed with Dr. Roberts' characterization of his role in the procedure, but asserted nevertheless that, as attending physician, Dr. Roberts had "ultimate responsibility" for the surgery.

\*219 Dr. Pachtman testified that she performed the first two procedures, the hysterectomy and entocele repair, without complication, although the entocele repair took longer than expected. Following the entocele repair, Dr. Roberts left the room to attend another operation that had been previously scheduled.

Dr. Pachtman then began the rectocele repair. Upon Dr. Pachtman's initial insertion into the levator ani muscle, the needle she was using broke. One-half to two-thirds of the needle, a length of about 1.5 cm, broke off and lodged somewhere within that muscle. Dr. Pachtman searched unsuccessfully for the broken portion of the needle for fifteen to twenty minutes. At that time, Dr. Roberts returned

and joined Dr. Pachtman in searching for the needle fragment.

Drs. Pachtman and Roberts utilized a silver probe to x-ray the affected area, in an attempt to locate the broken portion of the needle. After ascertaining the approximate location of the fragment, they decided to close the old incision and to continue their search through a new incision. After unsuccessfully searching for the needle for another forty-five minutes to one hour, they abandoned the search and closed the second incision. Both doctors indicated that they felt it was in the plaintiff's best interest to terminate the surgery at that point, even though they had failed to locate the needle fragment.

FN3. Dr. Pachtman cited plaintiff's substantial blood loss in and around the original incision as the reason for that decision.

Plaintiff testified that after the surgery Dr. Pachtman informed her of the needle breakage and stated that the needle was entrenched in the \*220 muscle and therefore could remain there without causing her any problems. However, after experiencing considerable pain and discomfort, plaintiff consulted with another physician, Dr. Frances Couch. Dr. Couch advised removing the needle fragment, and, subsequently, she performed the surgical procedure, successfully locating and removing the broken portion of the needle.

Plaintiff filed suit against Drs. Pachtman and Roberts, alleging negligence on various grounds, including the use of a needle that they knew or should have known was too small and failing to locate and remove the needle fragment. Plaintiff claimed that she suffers from severe pain, disfigurement, and limitation of body movement and functions, as well as experiencing mental and emotional distress. Plaintiff's husband, Danny Locke, filed a derivative claim.

In testimony presented at trial, plaintiff's expert

witness, Dr. Couch, was unable to identify any negligent conduct on the part of either Dr. Pachtman or Dr. Roberts. Dr. Couch also stated that she could not give an opinion regarding the adequacy of the needle size, because she had never viewed the needle intact. She explained that she could not identify the size of the needle without viewing the needle in its entirety.

FN4. Dr. Couch did not appear at trial, but a redacted version of her deposition was read into the record.

When questioned generally regarding the cause of needle breakage and its relation to the standard of care, Dr. Couch made two separate statements. At one point Dr. Couch stated that the standard of care did not relate to needle breakage at all, but rather to how one dealt with it, suggesting that needle breakage was simply one of the risks of surgery. Later, without relating this point to a standard of care, she noted that a surgeon's "incorrecttechnique" \*221 often \*\*789 causes a needle to break. When asked to describe what she meant by incorrect technique, Dr. Couch described instances in which a surgeon fails to manipulate the needle correctly, such as by inserting it at the wrong angle or applying too much force. Dr. Couch also testified that she had previously had a needle break while performing surgery.

In addition to Dr. Couch's expert testimony, plaintiff introduced evidence regarding a number of statements allegedly made by Dr. Pachtman following the surgery.

Plaintiff's brother, Reverend Gary Heniser, testified that, while he was at the hospital visiting his sister, Dr. Pachtman told him, "'I knew the needle was too small when I used it.'"

Coplaintiff Danny Locke testified that Dr. Pachtman had also spoken to him about the surgery: "[S]he told me that it was her fault, that she used the wrong needle, and she was sorry."

Finally, Shirley Locke testified that Dr. Pachtman

had told her:

"I knew that needle was too small when the new scrub nurse handed it to me. It wasn't her fault because she was new, but I chose to use it anyway and it's my fault and I am really sorry...." FN5

FN5. Although originally stating that these were Dr. Pachtman's exact words, plaintiff later retracted that characterization, asserting, instead, that the above quotation represented the substance of what Dr. Pachtman had conveyed to her.

Both Dr. Pachtman and Dr. Roberts testified at trial. Neither acknowledged any negligent behavior in the choice of needle, the needle breakage, or their subsequent search for the needle fragment.

At the close of plaintiff's proofs, the trial court granted defendants' motion for directed verdict on \*222 the ground that plaintiff had failed to make a prima facie showing regarding the standard of care. Plaintiff's motion for a new trial was denied, and, in a divided opinion, the Court of Appeals affirmed. This Court granted leave to appeal. 444 Mich. 885, 511 N.W.2d 687 (1993).

II

[1][2] Proof of a medical malpractice claim requires the demonstration of the following four factors: (1) the applicable standard of care, (2) breach of that standard of care by the defendant, (3) injury, and (4) proximate causation between the alleged breach and the injury. M.C.L. § 600.2912a; M.S.A. § 27A.2912(1). To survive a motion for directed verdict, the plaintiff must make a prima facie showing regarding each of the above elements.

FN6. M.C.L. § 600.2912a; M.S.A. § 27A.2912(1) provides:

In an action alleging malpractice the

plaintiff shall have the burden of proving that in light of the state of the art existing at the time of the alleged malpractice:

- (a) The defendant, if a general practitioner, failed to provide the plaintiff the recognized standard of acceptable professional practice in the community in which the defendant practices or in a similar community, and that as a proximate result of the defendant failing to provide that standard, the plaintiff suffered an injury.
- (b) The defendant, if a specialist, failed to provide the recognized standard of care within that specialty as reasonably applied in light of the facilities available in the community or other facilities reasonably available under the circumstances, and as a proximate result of the defendant failing to provide that standard, the plaintiff suffered an injury.

Plaintiff argues that the lower courts erred in finding that she had failed to demonstrate the standard of care applicable to defendants' conduct. Plaintiff contends that expert testimony was sufficient to establish this point, and, further, that the standard of care and breach of that standard were \*223 inferable under the doctrine of res ipsa loquitur and because the alleged negligence was within the common understanding of the jury.

We agree with the lower courts' determination that no prima facie showing was made, and therefore we affirm the directed verdict entered for the defendants.

Ш

[3] When evaluating a motion for directed verdict, the court must consider the evidence\*\*790 in the light most favorable to the nonmoving party, making all reasonable inferences in the nonmoving

party's favor. *Beals v. Walker*, 416 Mich. 469, 480, 331 N.W.2d 700 (1982).

Because different theories of recovery are involved, we will address the claims against each defendant individually.

#### Α

[4] Plaintiff argues first that the standard of care attributable to Dr. Pachtman was established by way of expert testimony. This Court has long recognized the importance of expert testimony in establishing a medical malpractice claim, and the need to educate the jury and the court regarding matters not within their common purview. As we have previously explained:

In a case involving professional service the ordinary layman is not equipped by common knowledge and experience to judge of the skill and competence of that service and determine whether it squares with the standard of such professional practice in the community. For that, the aid of expert testimony from those learned in the profession involved is required. [ *Lince v. Monson*, 363 Mich. 135, 140, 108 N.W.2d 845 (1961).]

\*224 While we have recognized exceptions to this requirement, the benefit of expert testimony, particularly in demonstrating the applicable standard of care, cannot be overstated.

In this case, plaintiff contends that the standard of care applicable to Dr. Pachtman was established by Dr. Couch's expert testimony. For this point, plaintiff relies on Dr. Couch's statement that needle breakage often occurs because of the surgeon's "incorrect technique." Plaintiff asserts that this testimony, coupled with Dr. Pachtman's admissions regarding use of a needle she knew to be too small, were sufficient to establish the standard of care and breach of that standard.

Dr. Couch's testimony with regard to the standard of care associated with needle breakage was rather

confused. At one point she suggested that needle breakage was merely one of the risks of surgery, and that needle breakage did not ordinarily signal a violation of the standard of care:

- Q. Do you feel that when a needle breaks off during a hysterectomy procedure as in this case that it is not a standard of care question but rather is just one of the contemplated risks of such surgery?
- A. Yes, that is correct. It's not a standard of care. You always know that there will be something, maybe some equipment failure but standard of care is how you deal with the situation.

Dr. Couch later testified that needle breakage may be attributable to a surgeon's "incorrect technique":

- Q. From your experience and your training can the manner in which a surgeon utilizes a needle cause it to break?
- A. I would say most of the time that's the case. It's a matter of incorrect technique.
- \*225 Q. Could you discuss that?
- A. Well, a needle is curved. If you forget the needle is curved and you push against the curve instead of with the curve the needle will break. If you try to put a needle through an instrument it doesn't go through steel. If it's not positioned correctly in a tissue and you're trying to draw it through against a clamp it will break. It will break ...

\* \* \* \* \* \*

A. Generally that's most of the reason why they break. You are putting force against where it wasn't made to be put against.

As the lower courts found, it is indeed questionable whether Dr. Couch's latter testimony on this point was sufficient to establish a standard of care with regard to "incorrect technique." Dr. Couch, while presenting one way in which needles break, never

went so far as to relate that discussion to a \*\*791 standard of care. In effect, she never explained what a reasonably prudent surgeon would do, in keeping with the standards of professional practice, that might not have been done by Dr. Pachtman. Accordingly, the jury would have had no standard against which to measure Dr. Pachtman's conduct. This factor, coupled with the conflicting nature of Dr. Couch's testimony, leads us to believe that the standard of care was not sufficiently established.

[5][6][7] We further note that Dr. Couch's explanation of how and why needles break, even had it established a standard of care, provides little support for the specific theory of negligence advanced by plaintiff in her complaint and at trial. While plaintiff argued that the needle broke in this case because it was of an inadequate size for the area to be sutured, Dr. Couch's description of "incorrect technique" leading to needle breakage related to \*226 the way the chosen needle is positioned and manipulated, regardless of its size. Dr. Couch did acknowledge at one point that there is such a thing as using a needle that is too small or too weak for a particular task.  $^{\rm FN7}$  However, she never related this to her theory of "incorrect technique," nor did she indicate that the needle utilized by defendants was of an inappropriate size. We find her statement, either standing alone or in conjunction with her testimony regarding incorrect technique, to be insufficient to establish a standard of care. Therefore, no prima facie showing was made. FN8

FN7. Dr. Couch testified regarding this point as follows:

- Q. Is there such a thing as a surgeon using a needle that's too small for the particular job at hand?
- A. Sure.
- Q. And when I say too small I mean utilizing a needle that may not be strong enough or big enough for the particular job at hand?

#### A. Correct.

FN8. Plaintiff also contends that the trial court erred in taking into account *defendant's* evidence in determining that expert testimony was not sufficient to establish a prima facie case. Specifically, plaintiff argues that the trial court improperly considered the testimony of defendant's expert, Dr. Floyd, who testified that no malpractice had been committed. Dr. Floyd's testimony was heard out of order because he could not be present at a later date.

In passing upon a motion for directed verdict, a trial judge must consider the evidence in plaintiff's favor unqualified by any conflicting evidence. The trial judge is not prohibited from considering evidence presented by a defense witness per se; rather, the judge may not consider evidence from any witness to the extent that it conflicts with evidence in plaintiff's favor. Here, however, it is clear that Dr. Floyd's testimony did not conflict with any in plaintiff's favor. In making his findings, the trial judge explicitly stated that there was no testimony that "points toward a breach of the standard of care expected of surgeons in cases such as this." Further, the trial judge also specifically found that defendant's expert had failed to identify any breach of the standard of conduct, noting, "Dr. Couch testified and did not make any statement on the testimony that I was able to review in which she indicated that there was any malpractice in this case." Accordingly, there was no error.

#### \*227 B

[8] Plaintiff next argues that the statements allegedly made by Dr. Pachtman were themselves sufficient to establish the standard of care and

breach of that standard. Plaintiff contends that her case is governed by this Court's decision in *Orozco* v. Henry Ford Hosp., 408 Mich. 248, 290 N.W.2d 363 (1980), and that, under the reasoning presented in *Orozco*, the lower courts erred in finding that defendant's admissions alone were insufficient to establish the standard of care.

Plaintiff's reliance upon *Orozco* is misplaced. In *Orozco*, the plaintiff testified that during his hernial surgery he heard one of the surgeons say, "Oops, I cut in the wrong place." *Id.* at 254, 290 N.W.2d 363. Following the surgery, one of his testicles atrophied. At trial, an expert witness testified that this injury was likely due to an impairment of the blood supply to the testicles during the surgery.

At the close of Orozco's proofs, the trial court granted the defendants' motion for a directed verdict, and the Court of Appeals \*\*792 affirmed, finding that the plaintiff had failed to make a prima facie showing of the applicable standard of care. This Court reversed the Court of Appeals by per curiam opinion. The Court found that expert testimony was not necessary because jury members would be able to determine, from their own common knowledge, whether the defendants' actions violated the applicable standard of care. As the Court explained:

FN9. In reaching this conclusion, the Court of Appeals relied on *Lince v. Monson, supra*. In *Lince*, this Court held that expert testimony was required in order for the jury to determine whether the defendants violated the standard of care when they mistakenly sutured the plaintiff's ureter in responding to excessive bleeding. 363 Mich. at 142, 108 N.W.2d 845.

Here Orozco offered the fact of the injury, a \*228 medical explanation of how that injury likely occurred, and an admission by the surgeon that he cut in the wrong place.

Paraphrasing Lince, "[t]he question is whether

the action of defendants conformed to standards of good practice in the community. Common knowledge and the experience of ordinary laymen do ... equip them to give the answer in a case such as this" when an expert testifies that the likely cause of injury was an impairment of the blood supply to the testicles in the course of the operation and the plaintiff testifies that the surgeon said, "Oops, I cut in the wrong place." [408 Mich. at 253-254, 290 N.W.2d 363. (Emphasis in original.)]

As is indicated above, the Court in Orozco did not rely exclusively upon the defendant's admission to find that a prima facie showing had been made. Rather, the Court found that on the basis of that admission and corroborating expert testimony the jury could determine from their own common knowledge whether the defendants' actions conformed to standards of professional practice. This decision was in line with previous case law holding that expert testimony is not normally required where the defendant mistakenly treated or did injury to a portion of the body that was free of disease and not designated for treatment. Sullivan v. Russell, 417 Mich. 398, 408, 338 N.W.2d 181 (1983) (no expert testimony was necessary where a dentist mistakenly ground three of the plaintiff's teeth not intended for treatment); Higdon v. Carlebach, 348 Mich. 363, 374, 83 N.W.2d 296 (1957) (expert testimony was not required where a dentist, using a rotating disk to separate two of the plaintiff's teeth, mistakenly cut into her tongue).

Turning to the present case, we hold that the lower courts correctly concluded that Dr. Pachtman's statements were insufficient to make a prima facie showing. While the statements may \*229 have indicated Dr. Pachtman's belief that she made a mistake or acted in error, a jury could not reasonably infer from those statements alone that Dr. Pachtman's actions did not conform to the standard of professional practice for the community as a whole.

FN10. We do not adopt the Court of Ap-

peals characterization of these statements as an "expression of her regret...." Unpublished opinion per curiam, decided February 17, 1993 (Docket No. 124648).

Unlike the situation presented in *Orozco*, the standard of care associated with needle choice and needle breakage is not accessible to the jury absent expert guidance. Plaintiff has provided no guidance with regard to what options were available to Dr. Pachtman and which of them she should have chosen. In short, there was no testimony regarding what a reasonably prudent surgeon would have done in Dr. Pachtman's situation. We agree with the Court of Appeals determination that the jury should not be left to speculate in this regard. It is precisely to avoid such speculation that expert testimony is ordinarily required.

Accordingly, without diminishing the holding in *Orozco*, we decline to extend it to the present case, in which the standard of care associated with the alleged negligence is not within the common knowledge of the jury, it cannot be reasonably inferred from the admissions alone, and where no further evidence was presented linking Dr. Pachtman's \*\*793 admissions to the standard of care. While it is conceivable that in some circumstances a doctor defendant's extrajudicial admissions could present prima facie evidence of breach of the standard of care, that is not the case here.

 $\mathbf{C}$ 

[9] Plaintiff next argues that even if expert testimony was insufficient, her case against Dr. Pachtman\*230 should have proceeded to the jury on the theory of res ipsa loquitur. Specifically, plaintiff contends, under this doctrine, a prima facie case was made, with regard to both the needle breakage and the fact that defendant terminated the surgery without having recovered the needle. The lower courts rejected these arguments, as do we.

As previously noted, while expert testimony is the

traditional and the preferred method of proving medical malpractice, exceptions to the need for expert testimony have been recognized. One such exception involves the doctrine of res ipsa loquitur. If a plaintiff's case satisfies the dictates of this doctrine, then the case may proceed to the jury without expert testimony.

This Court's decision in *Jones v. Porretta*, 428 Mich. 132, 405 N.W.2d 863 (1987), marked the Court's first explicit adoption and application of res ipsa loquitur in the medical malpractice context. FN11 In *Jones*, the Court cited the following four factors as necessary to a res ipsa loquitur claim:

FN11. However, as noted by the Court, the essential equivalent of the doctrine had long been recognized in this state under the guise of "'circumstantial evidence of negligence....'" *Id.* at 150, 405 N.W.2d 863.

- (1) the event must be of a kind which ordinarily does not occur in the absence of someone's negligence;
- (2) it must be caused by an agency or instrumentality within the exclusive control of the defendant;
- (3) it must not have been due to any voluntary action or contribution on the part of the plaintiff....
- (4) [e]vidence of the true explanation of the event must be more readily accessible to the defendant than to the plaintiff. [ *Id.* at 150-151, 405 N.W.2d 863.]

In the medical malpractice context, the crucial \*231 element, and that most difficult to establish, will often be the first factor, i.e., that the event is of a kind that does not ordinarily occur in the absence of negligence. A bad result will not *itself* be sufficient to satisfy that condition. As the Court explained:

This does not mean that a bad result cannot be presented by plaintiffs as part of their evidence of negligence, but, rather, that, standing alone, it is not adequate to create an issue for the jury. Something more is required, be it the common knowledge that the injury does not ordinarily occur without negligence or expert testimony to that effect. [ Id. at 154, 405 N.W.2d 863. (Emphasis added.)]

Therefore, the fact that the injury complained of does not ordinarily occur in the absence of negligence must either be supported by expert testimony or must be within the common understanding of the jury. Neither standard was met here.

Plaintiff first argues that expert testimony was sufficient for the jury to find that needle breakage does not ordinarily occur without negligence. We disagree. Even plaintiff's own expert acknowledged at one point that needle breakage is one of the risks of surgery, suggesting that faulty equipment might be a cause of breakage. Therefore no prima facie showing was made.

In the alternative, plaintiff contends that no expert testimony is required because it is within the common understanding of the jury that needles do not ordinarily break absent negligence. For this theory, plaintiff relies on this Court's holding in *LeFaive v. Asselin*, 262 Mich. 443, 247 N.W. 911 (1933). In *LeFaive*, the Court held that a jury could determine, without the aid of expert testimony, that the defendant's action in inadvertently\*\*794 \*232 leaving a needle within the plaintiff's incision violated the applicable standard of care.

Plaintiff's analogy to LeFaive is inapposite. In LeFaive, the act of leaving the needle within the incision was one of carelessness, from which negligence may easily be discerned. However, a far different situation is presented where a needle breaks off, and the surgeon, despite attempts to locate the fragment is unable to. One could not reasonably conclude, on the basis of common knowledge, that such an event does not ordinarily occur in the absence of negligence. Where negligence is not inferable through common knowledge, and where no expert testimony was presented to the effect that the

event complained of would not ordinarily occur without negligence, plaintiff's res ipsa loquitur claim must fail.

FN12. Plaintiff argues that the trial court impermissibly relied on a Missouri case, *Cebula v. Benoit*, 652 S.W.2d 304 (Mo.App., 1983), in determining that res ipsa loquitur does not apply in instances in which a needle breaks off during surgery and cannot be located by the surgeon. We can discern no impropriety in the court's reference to this decision for guidance.

D

[10] Lastly, plaintiff contends that a prima facie case was made against Dr. Pachtman because the negligence alleged was so gross as to be within the common understanding of the jury.

This Court has previously held that expert testimony may not be required when

"the lack of professional care is so manifest that it would be within the common knowledge and experience of the ordinary layman that the conduct was careless and not conformable to the standards of professional practice and care employed in the community." [Sullivan, 417 Mich. at 407, 338 N.W.2d 181, quoting Lince, 363 Mich. at 141, 108 N.W.2d 845.]

\*233 However, as was discussed in parts B and C, we do not find the standard of care with relation to Dr. Pachtman's allegedly negligent use of an inadequately sized needle to be within the common understanding of the jury. Nor do we find the standard of care applicable to defendants' decision to terminate the surgery, without having recovered the needle, to be ascertainable by the jury without the aid of expert testimony.

Е

Plaintiff asserts liability against Dr. Roberts on two grounds: (1) vicarious liability for the negligent acts of Dr. Pachtman, and (2) negligent supervision. However, plaintiff failed to establish a prima facie case under either standard.

[11] Plaintiff's vicarious liability claim fails because it presupposes negligent conduct on Dr. Pachtman's behalf. As previously discussed, plaintiff has failed to establish a prima facie case of liability against Dr. Pachtman.

[12] Plaintiff's negligent supervision claim is also not supported by the record. There was uncontroverted testimony, including testimony from plaintiff's own expert, to the fact that it was not unusual for an attending physician at University of Michigan Hospital to leave a resident alone during portions of a procedure. There was no testimony suggesting that such action was violative of a standard of care, nor do we find that point inferable by the jury. Therefore this claim is also without merit.

#### IV

We agree with the lower courts' determination that plaintiff failed to establish a prima facie case \*234 of medical malpractice against either Dr. Pachtman or Dr. Roberts.

We affirm.

MICHAEL J. CAVANAGH, C.J., and RILEY, BRICKLEY, BOYLE and ROBERT P. GRIFFIN, JJ., concur.

LEVIN, Justice (dissenting).

I agree with the majority that expert medical testimony concerning the standard of \*\*795 care and a breach was required. I also agree that the plaintiff did not establish a jury submissible question of fact on the basis of res ipsa loquitur or on the basis that the evidence of negligence was within the common understanding of the jury.

I would hold, however, that Dr. Judith A. Pachtman's statements to the effect that she knew the

needle that broke during surgery was too small when it was handed to her, and when she used it, were prima facie evidence of the standard of care and breach.

Ι

The question presented is whether Pachtman's statements-in effect admitting error but not in lawyer jargon such as "standard medical practice in this community"-are prima facie evidence of the standard of care and breach.

Plaintiff, Shirley Locke testified that Pachtman said that she knew the needle was too small when the new scrub nurse handed it to her, and Danny Locke testified that Pachtman said that she knew the needle was too small when she used it. Drawing all reasonable inferences in favor of Shirley Locke, a jury could reasonably conclude that Pachtman's statements conveyed her expert medical view that it was not sound medical practice in \*235 her community to use the particular needle she used in the surgery she was performing.

The majority concludes that Pachtman's statements may have expressed her belief that she violated her personal standard of care, and her personal standard of care may have been higher than the prevailing standard of care among physicians in the community.

Pachtman's statements may indeed have concerned her personal standard of care. It is no more probable, however, that the statements concerned her personal standard of care than that they concerned the generally applicable standard of care. The statements refer neither to a personal nor a general standard of care. The statements can reasonably be read either way, and a jury should decide the meaning of Pachtman's statements. In deciding a motion for a directed verdict, Pachtman's statements should be read favorably to the plaintiff, and thus as expressing Pachtman's expert medical view that a physician in her community would not have

used a needle of the size that she used for this particular surgery.

FN1. In *Wooten v. Curry*, 50 Tenn.App. 549, 552, 554, 362 S.W.2d 820 (1961), as distinguished from the instant case, the physician, under the law of Tennessee, was subject to liability for malpractice if his conduct fell below his personal standard of care. The plaintiff sought to establish the physician's personal standard of care by introducing the physician's statement that he "should" have examined the plaintiff sooner than he did.

The Tennessee Court of Appeals held that the statement was prima facie evidence of the physician's personal standard of care, and held that a jury must construe any ambiguity in the statement. In the court's words, "[t]he meaning of, and the weight to be given an admission or declaration against interest are generally questions for the jury."

The majority next contends that Pachtman's statements are not sufficient to establish the standard of care because the statements did not explain "what a reasonably prudent surgeon would \*236 have done in Dr. Pachtman's situation." But Pachtman's statements explain exactly what a reasonably prudent physician would have done in the same situation: a reasonably prudent physician would have used a larger needle. This is not a case in which a physician merely expressed general dissatisfaction with her overall performance or merely expressed regret.

II

Cases from other jurisdictions indicate that statements like Pachtman's-that confess error with reasonable specificity-are prima facie evidence of the standard of care and breach.

In *Greenwood v. Harris*, 362 P.2d 85, 87-88 (Okla., 1961), the plaintiff alleged that the \*\*796 physician erroneously diagnosed her pregnancy as a tumor, and then performed unnecessary surgery that left the plaintiff with an unsightly and painful scar. The plaintiff's only evidence concerning the standard of care was the physician's statements to the plaintiff and her husband that he "should have made more tests," and that he "wasn't satisfied with the lab report [and] *should have had the tests run again*, ... should have made some other tests." (Emphasis added.) The Oklahoma Supreme Court held that those statements alone were prima facie evidence of the standard of care and breach. The court said:

We can interpret these statements in no other way than as an admission that a faulty diagnosis had been made due to the failure of the defendant to use and apply the customary and usual degree of skill exercised by physicians in the community.

In \*237Woronka v. Sewall, 320 Mass. 362, 364, 69 N.E.2d 581 (1946), the plaintiff claimed that her physician negligently exposed the skin on her buttocks to irritating chemicals during the delivery of a child. The plaintiff's only evidence of the standard of care and breach was the physician's statements to the plaintiff and her husband that the plaintiff's burns resulted from "negligence when they [the plaintiff and the physician] were upstairs [in the delivery room]," and that the plaintiff's injury apparently occurred when a chemical solution was allowed to stay in contact with her skin for "too long a period." The physician argued that the word "negligence" did not supply the essential elements justifying a finding of liability.

The Supreme Judicial Court of Massachusetts held, however, that the plaintiff had produced sufficient evidence of the essential elements. The court reached this conclusion although the only testimony that explicitly mentioned the applicable standard of care came from a defense expert who opined that the use of the chemical that irritated the plaintiff was accepted medical practice in Boston at the time

of plaintiff's injury. FN3

FN3. In Sheffield v. Runner, 163 Cal.App.2d 48, 328 P.2d 828 (1958), a physician's statement that he should have put the patient in a hospital was held to be prima facie evidence of the standard of care and breach. In Wickoff v. James, 159 Cal.App.2d 664, 324 P.2d 661 (1958), a physician's statement that he "sure messed up" was held to be prima facie evidence of the standard of care and breach. In Robertson v. LaCroix, 534 P.2d 17, 19 (Okla.App., 1975), a physician's statement that he "just made a mistake and got over too far" during surgery was held to be prima facie evidence of the standard of care and breach.

In *Greenwood* and *Woronka*, the physicians' statements indicated with relative precision how they had erred. In *Greenwood*, the physician, in effect, confessed error in failing to administer certain tests for a second time in the face of inconclusive results, and, in *Woronka*, the physician\*238 stated that he improperly permitted the plaintiff's buttocks to stay in contact with a chemical irritant.

Other state supreme courts have found that the standard of care was not established by statements that fail to explain with relative precision what the physician should have done. In *Senesac v. Associates in Obstetrics & Gynecology*, 141 Vt. 310, 314-315, 449 A.2d 900 (1982), the plaintiff claimed that the physician had negligently performed an abortion. The plaintiff's only evidence of the standard of care was the physician's statement that she "had made a mistake, that she was sorry, and that it [the perforation of the uterus] had never happened before...." The Vermont Supreme Court held that the statement was not prima facie evidence of the standard of care.

In *Maxwell v. Women's Clinic*, 102 Idaho 53, 54, 625 P.2d 407 (1981), the plaintiff claimed that the defendant physician negligently performed a tubal

ligation. The plaintiff's only evidence regarding the standard of care was the physician's statement that he "obviously messed up." The Idaho Supreme Court held that summary judgment against the plaintiff was properly granted because \*\*797 the plaintiff did not present sufficient evidence of breach of the standard of care.

FN4. In *Cobbs v. Grant*, 8 Cal.3d 229, 238, 104 Cal.Rptr. 505, 502 P.2d 1 (1972), the physician's statement that he "blamed himself for [the plaintiff] being back in there [the hospital]" was held not to be prima facie evidence of the standard of care and breach.

In both *Maxwell* and *Senesac*, the physicians' statements did not explain relatively precisely-as did Pachtman's-how they had erred.

III

I conclude, consistent with precedent from other \*239 jurisdictions, that Pachtman's statement satisfied Locke's burden of presenting prima facie evidence of the standard of care and breach.

I would reverse the judgment of the Court of Appeals and remand for trial.

Mich.,1994. Locke v. Pachtman 446 Mich. 216, 521 N.W.2d 786, 42 A.L.R.5th 743

END OF DOCUMENT

Finally, I disagree with Justice Hawkins' statement on page 844 that "Blue Cross clearly had a reasonably arguable basis for denying the claim". This is simply not so, as the testimony at trial of Dr. J.B. Yeldell reflects. A more correct statement—one upon which I predicate my vote to deny the petition for rehearing (now that I understand that we are rejecting the formulation of law found in the majority opinion in Reserve Life in favor of one substantially similar to what I stated in my Reserve Life concurrence)-is: because there was evidence in the record sufficient under Paymaster Oil to prevent Plaintiff Campbell from obtaining a peremptory instruction in his favor on the liability features of the underlying contract claim (had that claim been litigated and not settled), Plaintiff Campbell was not entitled to have his bad faith refusal claim submitted to the jury. It is for this reason that I join now in holding that the trial judge erred in his refusal to grant Blue Cross' motion for judgment notwithstanding the verdict.

In spite of the above criticisms, I want to reiterate what I have said above. I regard Justice Hawkins' opinion as a substantial step out of the murky bog of the Step One-Two-Three formulations of *Reserve Life*. We simply need to go farther.

PRATHER and ANDERSON, JJ., join in this opinion.

DAN M. LEE, J., joins in result only.



ment of punitive damages should be submitted to a jury. Because in the case at bar the jury found against Campbell on the punitive damGlenn HALL, Husband of Terry O. Hall, Deceased

v.

Glyn R. HILBUN, M.D. No. 53784.

Supreme Court of Mississippi.

Feb. 27, 1985.

Husband of decedent, who died of adult respiratory distress syndrome, brought malpractice action against general surgeon who performed exploratory laporatomy on decedent. The Circuit Court, Jackson County, Darwin M. Maples, J., entered directed verdict for surgeon, and husband appealed. The Supreme Court, Robertson, J., held that: (1) surgeon acquired obligation to perform all facets of surgery with that level of competence and diligence as might be expected of minimally competent surgeons under the circumstances throughout the United States and to direct postoperative care and to insure that, with respect to all postoperative dangers or complications reasonably to be anticipated under circumstances, adequate provision was made for prompt diagnosis and treatment, and (2) each of two proffered medical experts should have been permitted to testify concerning physician's standard of care, even though they were from another region of the country.

Reversed and remanded for new trial. Hawkins, J., filed specially concurring opinion.

Patterson, C.J., filed opinion dissenting in part and concurring in part, in which Walker, P.J., joined the dissenting part.

Roy Noble Lee, P.J., filed opinion concurring in part and dissenting in part, in which Dan M. Lee, J., joined the concurring part, and Walker, P.J., joined dissenting part.

ages issue and because the matter has not been appropriately briefed, our answering these questions should await another day. ROBERTSON, Justice, for the Court:

I.

This matter is before the Court on Petition for Rehearing presenting primarily the question whether we should, as a necessary incident to a just adjudication of the case at bar, refine and elaborate upon our law regarding (a) the standard of care applicable to physicians in medical malpractice cases and (b) the matter of how expert witnesses may be qualified in such litigation. We greatly expanded the old locality rule in King v. Murphy, 424 So.2d 547 (Miss.1982). Experience and reason suggest that further refinements are necessary and in the interest of justice, generally and in this case.

When this matter was before the Court on direct appeal, we determined that the judgment below in favor of the surgeon, Dr. Glyn R. Hilbun, rendered following the granting of a motion for a directed verdict, had been correctly entered, two justices dissenting and two justices concurring specially. That result was perceived as required under our old locality rule, pre-King variety, pursuant to which the plaintiff's offer of the expert testimony of two eminently qualified physicians from Cleveland, Ohio, had been excluded.

For the reasons set forth below, we now regard that our original decision was incorrect. The opinion formally released on November 9, 1983, is withdrawn and instead thereof the instant opinion is substituted. The judgment of the Circuit Court is vacated and this case is remanded for a new trial on all issues.

II.

Terry O. Hall was admitted to the Singing River Hospital in Jackson County, Mississippi, in the early morning hours of May 18, 1978, complaining of abdominal discomfort. Because he was of the opinion his patient had a surgical problem, Dr. R.D.

 The Singing River Hospital and its administrator were dismissed on sovereign and public official immunity grounds, and no error relating thereto is assigned on appeal. The nurses were Ward, her physician, requested Dr. Glyn R. Hilbun, a general surgeon, to enter the case for consultation. Examination suggested that the discomfort and illness were probably caused by an obstruction of the small bowel. Dr. Hilbun recommended an exploratory laporatomy. Consent being given, Dr. Hilbun performed the surgery about noon on May 20, 1978, with apparent success.

Following surgery Mrs. Hall was moved to a recovery room at 1:35 p.m., where Dr. Hilbun remained in attendance with her until about 2:50 p.m. At that time Mrs. Hall was alert and communicating with him. All vital signs were stable. Mrs. Hall was then moved to a private room where she expired some 14 hours later.

On May 19, 1980, Glenn Hall commenced this wrongful death action by the filing of his complaint (nee declaration) in the Circuit Court of Jackson County, Mississippi. Named as defendants were Glyn R. Hilbun, M.D., and the Singing River Hospital, its administrator and several then unknown nurses.

This action was called for trial on July 13, 1981. Prior to that time all defendants with the exception of Dr. Hilbun had been dismissed. Not only was Dr. Hilbun the sole defendant at trial, he is the sole appellee here.

At trial Glenn Hall, plaintiff below and appellant here, described the fact of the surgery. He then testified that he remained with his wife in her hospital room from the time of her arrival from the recovery room at approximately 3:00 p.m. on May 20, 1978, until she ultimately expired at approximately 5:00 a.m. on the morning of May 21. Hall stated that his wife complained of pain at about 9:00 p.m. and was given morphine for relief, after which she fell asleep. Thereafter, Hall observed that his wife had difficulty in breathing which he reported to the nurses. He inquired if something was wrong and was told his

not named originally, and plaintiff never amended to name them or have them served with process. wife was all right and that such breathing was not unusual following surgery. The labored breathing then subsided for an hour or more. Later, Mrs. Hall awakened and again complained of pain in her abdomen and requested a sedative, which was administered following which she fell asleep. Mrs. Hall experienced further difficulty in breathing, and her husband reported this, too. Again, a nurse told Hall that such was normal, that patients sometimes make a lot of noise after surgery.

After the nurse left the following occurred, according to Hall.

[A]t this time I followed her [the nurse] into the hall and walked in the hall a minute. Then I walked back into the room, and walked back out in the hall. Then I walked into the room again and I walked over to my wife and put my hand on her arm because she had stopped making that noise. Then I bent over and flipped the light on and got closer to her where I could see her, and it looked like she was having a real hard problem breathing and she was turning pale or a bluish color. And I went to screaming.

Dr. Hilbun was called and came to the hospital immediately only to find his patient had expired. The cause of the death of Terry O. Hall was subsequently determined to be adult respiratory distress syndrome (cardio-respiratory failure).

Dr. Hilbun was called as an adverse witness and gave testimony largely in accord with that above. He stated Dr. Ward requested consultation concerning Mrs. Hall's illness. He related that his diagnosis of a blocked intestine was correct, as revealed by the surgery, and that the surgery was a success. He testified that a surgeon operating in the Singing River Hospital was assisted by the nurses in the surgical ward who were on duty at the time, and that he had no option in their selection, had no way of knowing their qualifications, but did assume they were competent because they were selected by the hospital for duty in the surgical ward.

Dr. Hilbun stated the surgery was performed on a Saturday. Following the pa-

tient's removal to her room, he "went home and was on call that weekend for anything that might come up." Dr. Hilbun made no follow-up contacts with his patient, nor did he make any inquiry that evening regarding Mrs. Hall's post-operative progress. Moreover, he was not contacted by the nursing staff or others concerning Mrs. Hall's condition during the afternoon or evening of May 20 following surgery, or the early morning hours of May 21, although the exhibits introduced at trial disclose fluctuations in the vital signs late in the evening of May 20 and more so, in the early morning hours of May 21. Dr. Hilbun's next contact with his patient came when he was called by Glenn Hall about 4:55 or 5:00 that morning. By then it was too late.

Ironically, during those early morning hours of May 21, Dr. Hilbun was called by a member of the nursing staff concerning a patient who was in a room adjoining Mrs. Hall's, but Dr. Hilbun was not advised of Mrs. Hall's condition and apparently he did not inquire.

The autopsy performed upon Mrs. Hall's body revealed the cause of death and, additionally, disclosed that a laporatomy sponge had been left in the patient's abdominal cavity. The evidence, however, without contradiction establishes that the sponge did not contribute to Mrs. Hall's death. Although the sponge may ultimately have caused illness, this possibility was foreclosed by the patient's untimely death.

Plaintiff's theory of the case centered around the post-operative care provided by Dr. Hilbun. Two areas of fault suggested were Dr. Hilbun's failure to make inquiry regarding his patient's post-operative course prior to his retiring on the night of May 20 and his alleged failure to give appropriate post-operative instructions to the hospital nursing staff.

When questioned at trial, Dr. Hilbun first stated that he had practiced for 16 years in the Singing River Hospital and was familiar with the routine of making surgical notes, i.e., a history of the sur-

gery. He explained that the post-operative orders were noted on the record out of courtesy by Dr. Judy Fabian, the anesthesiologist on the case. He stated such orders were customarily approved by his signature or he would add or subtract from the record to reflect the exact situation.

Dr. Hilbun was asked to read the postoperative orders as noted on May 20, 1978. In pertinent part, his response follows:

- Q. Okay, is that done in a shorthand form?
- A. To RR; that means to recovery room.
- Q. Okay.
- A. That is an accepted abbreviation. All right, (2) vital signs every fifteen minutes until stable, then hourly times four, then routinely. (3) NPO. That means nothing by mouth. (4) Intake and output.
- Q. Just a second. Intake and output; what does that particular order mean? A. This woman has a levin tube in, and she has a Foley catheter in her bladder. She has I.V.s in her arm. We like to know exactly how much is going in and how much is coming out so we can keep up with her fluid balance. She is not going to be eating for several days. Q. The tube is going down her nose, where was that tube going to?
- A. To her stomach.
- Q. Into her stomach. And what were the other two tubes that she had now? A. She had a Foley catheter. That's a catheter in your bladder. It is put there for several reasons. One is to keep up with the intake and output; the other is to get the bladder out of the way, because you don't want to operate on someone with a full bladder and have the bladder in the way.
- Q. Okay, is there another tube in her with intravenous fluids?
- A. I.V. fluids; yes.
- Q. So the I & O abbreviation there is to keep up with the intake and output?

  A. Right.
- Q. Okay, go to the next one.

- A. Hemoglobin and (inaudible) in the morning. That is a blood count the next morning.
- Q. That was to be done on the 21st; the next morning?
- A. Right. (6) Bed rest. Ambulate in a.m. That means to get her up and walk her in the morning. As I mentioned before, nasogastric tube—the tube from your nose to your stomach. We scope to suction. That's to keep the stomach empty.
- Q. So the jury will understand later, that is again abbreviated N-G?
- A. N-G tube. That's the common abbreviation. Okay, insert Foley catheter. We have talked about the Foley catheter. Run D-5 (inaudible) at 125 c.c.'s per hour.
- Q. Would you explain what that means, please?
- A. Okay. That's I.V. fluids. Okay, we run at 125 cc's per day. If you ran 100 cc's per hour and you had ten of those, that would be a ten hour bottle. So this is going to run less than ten hours. We will say around seven hours, or something like that. We know we can regulate it. We have a cc dropper. We know exactly how many cc's drops in per hour. We know how much fluid is going in per hour.
- Q. Okay. And the next order?
- A. The post-operative medication that we give for pain is morphine, 10 milligrams; that is a unit of measurement. And Phenergan, which is 25 milligrams. Phenigan is a kind of an anahistamene [sic] tranquilizer, anti-nausea to keep you from vomiting. If you add it with the morphine, it really cuts down the vomiting and post-operative nausea. This is to be given i.m.—in the muscle—every four hours as needed for pain. The next one—
- Q. —One moment before you go on. That simply means when the patient is in pain she can have that intra-muscular, but no more often than every four hours?
- A. Right.

- Q. Okay, go ahead.
- A. If she doesn't need it, she doesn't have to have it. The next one is number
- 12, Keflin, which is antibiotic, 1 gram
- I.V. every six hours.
- Q. The morphine now was for pain?
- A. Right.
- Q. What was the second medication?
- A. Phenergan.
- Q. That is to help her sleep?
- A. That's an anti-nausea.
- Q. And the Keflin, what was the reason for that?
- A. Some physicians like to give prophylactic antibiotics after a serious operation or major surgery; some don't. I'm from the school that I had rather prevent an infection before it gets there, than have to start treating it after it gets wound up and everything.
- Q. Keflin is an antibiotic that is used with great regularity in the hospitals, especially with post-surgery; is that right?
- A. Right.
- Q. Now after this surgery, while Mrs. Hall was in the recovery room did I understand you to say earlier that you checked on her there?
- A. When I got through operating on Mrs. Hall, with this major surgical procedure in an emergency situation—and I always do—I went to the recovery room with Mrs. Hall, stayed in the recovery room with Mrs. Hall, listened to her chest, took her vital signs, stayed there with her and discharged her to the floor. The only time I left the recovery room was to go into the waiting room and tell Mr. Hall. Mrs. Hall waked up, I talked to her, she said she was cold. She was completely alert.
- Q. Now, you went to the recovery room to see her because you were still her physician following her post-surgery?
- A. I was one of her physicians. I operated on her, and I go to the recovery room with everybody.
- Q. Okay. You were the surgeon and you were concerned about the surgical

- procedures and how she was doing postoperatively, or either you are not concerned with your patients, how they do post-operatively?
- A. As I said, I go to the recovery room with every one of my patients.
- Q. Then you are still the doctor?
- I was one of her physicians.
- Q. Okay. And you customarily follow your patients following the surgery to see how they are doing as a result of the surgery, because you are the surgeon. Is that correct?
- A. Yes.
- . . .
- Q. Let's talk about Terry Hall.
- A. In the recovery room?
- Q. All right. You followed her to the recovery room?
- A. Yes, I sure did.
- Q. Okay. Were you through with her after she came out of the recovery room?
- A. No.
- Q. How long do you follow a patient like Terry Hall?
- A. Until she leaves the hospital.
- Q. Okay. So ever how long she is in the hospital, you are going to continue to see her?
- A. As long as my services are needed. Insofar as the record reflects, Dr. Hilbun gave the nursing staff no instructions regarding the post-operative monitoring and care of Mrs. Hall beyond those detailed in his testimony quoted above. Dr. Hilbun had no contact with Mrs. Hall after 3:00 p.m. on May 20. Fourteen hours later she was dead.

The plaintiff called Dr. S.O. Hoerr, a retired surgeon of Cleveland, Ohio, as an expert witness. The record reflects that Dr. Hoerr is a cum laude graduate of the Harvard Medical School, enjoys the respect of his peers, and has had many years of surgical practice. Through him the plaintiff sought to establish that there is a national standard of surgical practice and surgical care of patients in the United States to which all surgeons, including Dr. Hilbun,

are obligated to adhere. Dr. Hoerr conceded that he did not know for a fact the standard of professional skill, including surgical skills and post-operative care, practiced by general surgeons in Pascagoula, Mississippi, but that he did know what the standard should have been.

Relying on *Dazet v. Bass*, 254 So.2d 183 (Miss.1971), which at the time [July 13, 1981] was this Court's latest utterance on the subject of who may testify as an expert witness in a medical malpractice action, the trial court ruled that Dr. Hoerr was not qualified to give an opinion as to whether Dr. Hilbun's post-operative regimen departed from the obligatory standard of care. In his ruling the trial judge made the following statement:

I think the local rule [the locality rule] has been applied too restrictively in this state, and my basic belief is that it has got to be enlarged. But I don't believe our Supreme Court has gone that far and I personally don't think it can be applied nationally. Anyway, that is left up to the Supreme Court and I hope this case will help verify that.

Thereafter, the plaintiff made an extensive question and answer proffer of Dr. Hoerr's testimony.

Dr. David Peter Lango Sachs, also of Cleveland, Ohio, was offered by the plaintiff as a witness, and it appears that he was eminently qualified in his specialty of pulmonary diseases. He also was unfamiliar with the standard of care in Pascagoula, Mississippi, although well versed in the national standards. Dr. Sachs was not permitted to testify because of this court's ruling in Dazet v. Bass. An appropriate proffer of Dr. Sachs' testimony was made by plaintiff.

Parts of Dr. Hoerr's testimony excluded under the trial judge's ruling follow:

A. My opinion is that she [Mrs. Hall] did not receive the type of care that she should have received from the general surgical specialist and that he [Dr. Hilbun] was negligent in not following this patient; contacting, checking on the condition of his patient sometime in the eve-

ning of May 20th. It is important in the post-operative care of patients to remember that very serious complications can follow abdominal operations, in particular in the first few hours after a surgical procedure. And this can be inward bleeding; it can be an explosive development in an infection; or it can be the development of a serious pulmonary complication, as it was in this patient. As a result of her condition, it is my opinion that he lost the opportunity to diagnose a condition, which in all probability could have been diagnosed at the time by an experienced general surgeon, one with expertise in thoracic surgery. And then appropriate treatment could have been undertaken to abort the complications and save her life.

There are different ways that a surgeon can keep track of his patient-"follow her" as the expression goes-besides a bedside visit, which is the best way and which need not be very long at all, in which the vital signs are checked over. The surgeon gets a general impression of what's going on. He can delegate this responsibility to a competent physician, who need not be a surgeon but could be a knowledgeable family practitioner. He could call in and ask to speak to the registered nurse in charge of the patient and determine through her what the vital signs are, and if she is an experienced Registered Nurse what her evaluation of the patient is. From my review of the record, none of these things took place, and there is no effort as far as I can see that Dr. Hilbun made any effort to find out what was going on with this patient during that period of time. I might say or add an additional belief that I felt that the nursing responsibility which should have been exercised was not exercised, particularly at the 4:00 a.m. level when the pulse rate was recorded at 140 per minute without any effort as far as I can see to have any physician see the patient or to get in touch with the operating surgeon and so on.

There is an additional thing that Dr. Hilbun could have done if he felt that the nursing services might be spotty-sometimes good, sometimes bad. This is commonly done in Columbus, Ohio, in Ashtabula, Pascagoula, etcetera. He could put limits on the degree in which the vital signs can vary, expressing the order that he should be called if they exceeded that. Examples would be: Call me if the pulse rate goes over 110; call me if the temperature exceeds 101; call me if the blood pressure drops below 100. There is a simple way of spelling out for the nursing services what the limits of discretion belong to them and the point at which the doctor should be called.

Q. Dr. Hoerr, the post-operative orders in the records that you have—I believe they are the yellow sheets toward the front. (Looking for order) Now, I have directed your attention to the post-operative orders of Dr. Hilbun, which have previously been identified by him as that. Have you had an opportunity to review the post-operative orders?

A. Yes, I have.

Q. Were there any orders in there at any place, or any other place in the records for that matter, in which Dr. Hilbun directed anyone to contact him if there were certain changes in vital signs?

A. Not that I could find. The answer is no. I couldn't see any there.
[emphasis added]

Dr. Hilbun did not place any orders on the chart for the nurses to call him in the event of a change in the vital signs of Mrs. Hall. He normally made afternoon rounds between 4:00 and 5:00 p.m. but didn't recall whether he went by to see her before going home. Dr. Hilbun was on call at the hospital that weekend for anything which might come up. Subsequent to the operation and previous to Mrs. Hall's death, he was called

2. By agreement of the parties, Dr. Dohn testified "out of turn". The record reflects that other professional obligations of Dr. Dohn would have rendered his appearance any other time extremely inconvenient. The trial judge and the about one other person on the same ward, one door down, twice during the night. He made no inquiry concerning Mrs. Hall, nor did he see or communicate with her.

Dr. Donald Dohn, of expertise unquestioned by plaintiff and with years of practical experience, gave testimony for the defendant. He had practiced on the staff at the Cleveland Clinic Foundation in Cleveland, Ohio, beginning in 1958.2 Fortuitously, he had moved to Pascagoula, Mississippi, about one month before the trial. Dr. Dohn stated he had practiced in the Singing River Hospital for a short time and there was a great difference in the standard of care in medical procedures in Cleveland, Ohio, and those in Pascagoula, Mississippi. Although he had practiced three weeks in Pascagoula, he was still in the process of acquainting himself with the local conditions. He explained the differences as follows:

Well, there are personnel differences. There are equipment differences. There are diagnostic differences. There are differences in staff responsibility and so on. For example, at the Cleveland Clinic on our service we had ten residents that we were training. They worked with us as our right hands. Here we have no staff. So it is up to us to do the things that our residents would have done there. There we had a team of five or six nurses and other personnel in the operating room to help us. Here we have nurses in the operating room, but there is no assigned team. You get the luck of the draw that day. I am finding out these things myself. Up there it is a big center; a thousand beds, and it is a regional center. We have tremendous advantages with technical systems, various types of x-ray equipment that is [sic] sophisticated. Also in terms of the intensive care unit, we had a Neurosurgical Intensive Care with people who were spe-

parties appropriately respected Dr. Dohn's convenience. In any event, this is why we have before us the testimony of a defense expert, even though the trial ended with the direction of a verdict at the end of plaintiff's case.

cially trained as a team to work there. From my standpoint personally, I seldom had to do much paperwork there as compared to what I have to do now. I have to dictate everything and take all my notes. So, as you can see, there is a difference.

Finally, he again stated the standard of care in Ohio and the standard of care in the Singing River Hospital are very different, although it is obvious to the careful reader of Dr. Dohn's testimony that in so doing he had reference to the differences in equipment, personnel and resources and not differences in the standards of skill, medical knowledge and general medical competence a physician could be expected to bring to bear upon the treatment of a patient.

At the conclusion of the plaintiff's case, defendant moved for a directed verdict on the obvious grounds that, the testimony of Drs. Hoerr and Sachs having been excluded, the Plaintiff had failed to present a legally sufficient quantum of evidence to establish a prima facie case. The Circuit Court granted the motion and on July 17, 1981, final judgment was entered in favor of Defendant, Glyn R. Hilbun, and against Glenn Hall, husband of Terry O. Hall, the deceased.

In due course thereafter, Hall filed a motion for a new trial which on September 11, 1981, was overruled and denied. Hall then timely perfected his appeal to this Court.

#### III.

#### A. General Considerations

[1-4] Medical malpractice is legal fault by a physician <sup>3</sup> or surgeon. It arises from the failure of a physician to provide the quality of care required by law. When a physician undertakes to treat a patient, he takes on an obligation enforceable at law to use minimally sound medical judgment and render minimally competent care in the course of the services he provides. A phy-

For convenience here, we use the term physician to include all persons possessing an M.D.

sician does not guarantee recovery. If a patient sustains injury because of the physician's failure to perform the duty he has assumed under our law, the physician may be liable in damages. A competent physician is not liable *per se* for a mere error of judgment, mistaken diagnosis or the occurrence of an undesirable result.

The twin principles undergirding our stewardship of the law regulating professional liability of physicians have always been reason and fairness. For years in medical malpractice litigation we regarded as reasonable and fair what came to be known as the "locality rule" (but which has always consisted of at least two separate rules, one a rule of substantive law, the other a rule of evidence).

First, under the locality rule, we have heretofore recognized as a rule of substantive law that a physician is bound to bestow to each patient such reasonable and ordinary care, skill, and diligence and to exercise such good medical judgment as physicians and surgeons in good standing in the same neighborhood or locality, in the same general line of practice, ordinarily have and exercise in like cases. Hill v. Stewart, 209 So.2d 809, 812 (Miss.1968); DeLaughter v. Womack, 250 Miss. 190, 202, 164 So.2d 762, 766 (1964); Copeland v. Robertson, 236 Miss. 95, 110, 112 So.2d 236, 241 (1959).

Second, as a rule of evidence, we have heretofore held that, in addition to possessing all of the other qualities requisite for judicial acceptance as an expert witness generally, a medical expert would not be allowed to testify in a medical malpractice case unless he practiced in the neighborhood or locality and was familiar with the local standard of care. See Holmes v. Elliott, 443 So.2d 825, 827-833 (Miss.1983); King v. Murphy, 424 So.2d 547, 549-550 (Miss.1982).

Both "prongs" of the locality rule have fallen under attack in recent years. It is urged that the circumstances which have

and providing medical or surgical services.

Cite as 466 So.2d 856 (Miss. 1985)

given rise to the rules have passed out of existence. The practice of medicine in general and medical malpractice litigation in particular are said to have achieved a level sophistication that require a modernization of our law. There is merit in the attack. Suffice it to say that the rules we have heretofore employed do not seem nearly so consonant with reason and fairness as they once did.

Just over two years ago we recognized that all was not well in this troubled area of the law. In King v. Murphy, 424 So.2d 547 (Miss.1982), we greatly expanded the concept of the "neighborhood or locality", within the contemplation of the substantive rule regulating the standard of care, to include geographically at least the entire state of Mississippi plus "a reasonable distance adjacent to state boundaries." 424 So.2d at 550. (emphasis added).

King also removed the geographical restrictions on the pool from which expert witnesses might be drawn by either adversary. King held that

an expert witness who is knowledgeable of, and familiar with, the statewide standard of care shall not have his testimony excluded on the ground that he does not practice in this state.

424 So.2d at 550 (emphasis added).

Under King an otherwise competent medical expert, say, from New York, would be eligible to testify if he had, prior to taking the witness stand, substantially familiarized himself with the standard of care in the (greatly enlarged) "locality or neighborhood".

Since King, the docket of this Court has continued to be supplied with medical malpractice cases, a number of which are pending at this time. In the light of these cases, and the excellent briefs and arguments we have received from counsel, several things are apparent:

First, King recognizes that the locality rule is not and has never been just one

4. A most immediate example of this mis-reading of King is that of Appellee Hilbun. In his brief filed February 9, 1984, at page 17, counsel for Dr. Hilbun reads King as allowing the expert rule. King draws a distinction between the substantive rule of law governing the liability vel non of physicians and the rule of evidence regulating the appearance of expert witnesses. In this sense King establishes a satisfactory general framework within which to handle these cases in the future.

Second, regarding the substantive standard, reflection suggests that further refinement and clarification are necessary. More sharpness needs to be brought to the distinction between the level of care a physician may be expected to render by reference to his skill, knowledge, judgment and general competence, on the one hand, and that which may reasonably be expected by reference to the facilities, equipment, personnel and resources reasonably available to him in the course of treatment. On the point of reasonable availability of resources, there are great variances from rural to urban areas within the King-defined "locality or neighborhood". These need be taken into account. Further, for the sake of intellectual honesty, we should go ahead and state forthrightly what everyone who has read King surely knows: that the "locality or neighborhood" concept as we have heretofore known it has been obliterated.

Third, King's evidentiary rule regulating expert witnesses seems clear to us. The cases that have come before the Court since King, however, suggest that it is not wholly understood in some quarters. On this point, we wish to make it clear that King means what it says: where a proffered medical expert lives or practices per se has no relevance to whether he may give expert opinion testimony at trial.

#### B. The Experience In Other States

Our law is not administered in isolation, any more than the physicians who practice in this state work in isolation from the rest of the country. We are not the first state to confront these problems.

testimony only by "a physician who practices within a reasonable distance adjacent to state boundaries, [and] who is...."

No doubt there was a time when all states embraced what has been simplistically denominated "the locality rule". Formulated over a hundred years ago to protect the rural and small town practitioner presumed to be less adequately informed and equipped than his colleague in the city the rule gradually came to hold sway throughout the country. See, e.g., Small v. Howard, 128 Mass. 131, 132, 35 Am.Rep. 363, 365 (1880); Smothers v. Hanks, 34 Iowa 286, 289-90, 11 Am.Rep. 141, 142-43, (1872).

Times have changed and perceptions of reality have changed. We now have a plethora of varying rules enforced among the fifty states in medical malpractice cases. Some states have opted for what has come to be known as the "national standard of care". See, e.g., Drs. Lane, Bryant, Eubanks & Dulaney v. Otts, 412 So.2d 254, 257-58 (Ala.1982); Morrison v. MacNamara, 407 A.2d 555, 565 (D.C.1979); Greenstein v. Meister, 279 Md. 275, 368 A.2d 451, 456-57 (1977); see also Martin v. Bralliar, 36 Colo.App. 254, 259, 540 P.2d 1118, 1121 (1975) (national standard applied to the facts in this case); Brune v. Belinkoff, 354 Mass. 102, 108-09, 235 N.E.2d 793, 798 (1968) (national standard modified by local facility limitations); Hart v. Steele, 416 S.W.2d 927, 931 (Mo.1967) (same); Pederson v. Dumouchel, 72 Wash.2d 73, 79, 431 P.2d 973, 977-78 (1967) (same); cf. McCormack v. Lindberg, 352 N.W.2d 30, 36 (Minn.Ct.App.1984) (national standard applied to specialists); Moultrie v. Medical University of South Carolina, 280 S.C. 159, 311 S.E.2d 730, 731 (1984) (same); Taylor v. Hill, 464 A.2d 938, 943 (Me.1983) (same); Steinbach v. Barfield, 428 So.2d 915, 919-20 (La.Ct.App.1983) (same); Wentling v. Jenny, 206 Neb. 335, 338-39, 293 N.W.2d 76, 79 (1980) (same); Orcutt v.

5. As a practical matter there is often little difference between this "similar community" standard and the "national" standard. See Goffe v. Pharmaseal Laboratory, Inc., 90 N.M. 764, 767, 568 P.2d 600, 604 (1976) (Washington doctor, who testified that medicine was practiced in Washington in a manner similar to Albuquerque, New Mexico, could describe the standard of care applicable to Albuquerque).

Miller, 95 Nev. 408, 595 P.2d 1191, 1194–95 (1979) (same); Gaston v. Hunter, 121 Ariz. 33, 54–55, 588 P.2d 326, 346 (1978) (same); Simpson v. Davis, 219 Kan. 584, 587–88, 549 P.2d 950, 953–54 (1976); Bruni v. Tatsumi, 46 Ohio St.2d 127, 134–35, 346 N.E.2d 673, 679 (1976) (same); Kronke v. Danielson, 108 Ariz. 400, 403, 499 P.2d 156, 159 (1972) (same); Naccarato v. Grob, 384 Mich. 248, 253, 180 N.W.2d 788, 791 (1970) (same).

The law in other states has imposed a uniform statewide standard of care. See, e.g., Fitzmaurice v. Flynn, 167 Conn. 609, 617, 356 A.2d 887, 892 (1975); Ives v. Redford, 219 Va. 838, 842, 252 S.E.2d 315, 318 (1979).

Still other states have expanded the locality rule to require that a physician possess and exercise that degree of skill and care which a physician of ordinary prudence and skill, practicing in the same or a similar community, would have exercised in the same or similar circumstances.<sup>5</sup> See, e.g., Baylis v. Wilmington Medical Center, Inc., 477 A.2d 1051, 1057 (Del.1984); Bartimus v. Paxton Community Hospital, 120 Ill.App.3d 1060, 76 Ill.Dec. 418, 424, 458 N.E.2d 1072, 1078 (1983); McPherson v. Ellis, 305 N.C. 266, 270, 287 S.E.2d 892, 895 (1982); Jenkins v. Parrish, 627 P.2d 533, 537 (Utah 1981); Priest v. Lindig, 583 P.2d 173, 176 (Alaska 1978); Chandler v. Neosho Memorial Hospital, 223 Kan. 1, 3-4, 574 P.2d 136, 138 (1977); Kortus v. Jensen, 195 Neb. 261, 269, 237 N.W.2d 845, 850 (1976); Gambill v. Stroud, 258 Ark. 766, 770-71, 531 S.W.2d 945, 948-49 (1976); Groffe v. Pharmaseal Laboratories, Inc., 90 N.M. 764, 767, 568 P.2d 600, 603-04 (1976); see also Haught v. Maceluch, 681 F.2d 291, 303 (5th Cir.1982) (applying Texas law).6

6. States such as Arizona and Kansas, for examples, employ this "similar community" standard only to general practitioners, and hold specialists to a "national" standard; Kronke v. Danielson, 108 Ariz. 400, 403, 499 P.2d 156, 159 (1972) ("similar community" for general practitioners and "national" for specialists); compare Chandler v. Neosho Memorial Hospital, 223 Kan. 1, 3-4, 574 P.2d 136, 138 (1977) ("similar communi-

Finally there are states which doggedly cling to the old locality rule. See, e.g., Campbell v. Oliva, 424 F.2d 1244, 1248 (6th Cir.1970) (applying Tennessee law).

We have carefully considered these and other cases together with the excellent briefs of counsel in this and several related cases now pending before the court. We hope that today's opinion will reflect that we have learned from the mistakes and experiences of others, as well as our own.

One mistake many have made has been the attempt to simplify that which is not so simple. Among such mistakes have been the pretention that the locality rule was a single rule, the use in a rule of the phrase "standard of care" accompanied at most by an amorphous formulation of that standard, and the adoption of a "national standard of care" without explaining what is meant thereby or taking account of the realities of the universe in which physician and patient interact. Courts seldom advance the cause of justice when they forge unrealistically simplistic rules to regulate subtly complex activities and enterprises. Such efforts create more problems than they solve.

In the analysis and formulations that follow, we seek clarity, which is not always synonymous with simplicity. We seek a sensitive accommodation of the legitimate interests, on the one hand, of those who have taken and take seriously the Oath of Hippocrates, and on the other hand, of those who seek and receive health care. By the same token, we hope that today's opinion will reflect that reason and fairness have subsumed passion and self-interest as the pillars upon which our rules of law ought to be based.

C. The Physician's Duty of Care: A primary rule of substantive law

#### 1. The Backdrop

[5,6] Each physician, by virtue of the positive, substantive law of this state, has a

duty of care consistent with the level of expertise the physician holds himself out as possessing and consistent with the circumstances of the case. That duty is non-delegable. See Pharr v. Anderson, 436 So.2d 1357, 1361 (Miss.1983). It is owing to each patient he or she undertakes to treat, and in that regard the patient has a correlative right. Injury caused by substantial violations of the physician's duty and the patient's right may subject the physician to tort liability.

[7] Liability turns on a failure to provide the required level of care. It matters not whether this failure results from incompetence or negligence. Some of our cases have misleadingly stated that liability may result from either of two causes: "lack of skill or neglect to apply it if possessed". Dazet v. Bass, 254 So.2d 183, 186 (Miss.1971); DeLaughter v. Womack, 250 Miss. 190, 202, 164 So.2d 762, 767 (1964); Newport v. Hyde, 244 Miss. 870, 875, 147 So.2d 113, 115 (1962). The matter is properly seen from the patient's point of view. Liability results from the physician's failure to provide requisite care under the circumstances, and nothing turns on whether this failure resulted from incompetence or neglect.

Our law has long focused upon the quality of care a physician's knowledge and skill may enable him to render. Repeatedly in our cases we find the statement that

a physician must possess that reasonable degree of learning, skill and experience which is ordinarily possessed by others in his profession.

Hill v. Stewart, 209 So.2d 809, 812 (Miss. 1968); DeLaughter v. Womack, 250 Miss. 190, 201–202, 164 So.2d 762, 766 (1964); Copeland v. Robertson, 236 Miss. 95, 110, 112 So.2d 236, 241 (1959).

In its modernization of our previous rule, King v. Murphy uses the same starting point. 424 So.2d at 549.

ty" standard for general practitioners) with Simpson v. Davis, 219 Kan. 584, 587-88, 549 P.2d

950, 953-54 (1976) ("national" standard for specialists).

The locality rule was superimposed upon this obviously valid general premise. We perceived physicians as more or less isolated in their local communities and held the level of care they were obligated to render was that generally prevailing in the community. By custom, physicians in each community were empowered to set the standards by which their professional conduct would be judged.

#### 2. The Inevitable Ascendency of National Standards

In 1971, we faced a strong attack on the continuing validity and viability of the locality rule in *Dazet v. Bass*, 254 So.2d 183 (Miss.1971). On that occasion we were advised

that physicians now attend the same colleges, receive the same post graduate courses in their specialities, and go to the same seminars, that the standards of care for a specialist should be and are the same throughout the country, and that geographical conditions or circumstances are no longer valid as controlling the standards of a specialist's care or competence.

254 So.2d at 187.

Though we rejected plaintiff's case on procedural grounds, we recognized in *Dazet* that the point has "considerable force". 254 So.2d at 187. The continued force of the point is evidenced by the step forward taken in *King v. Murphy*.

We would have to put our heads in the sand to ignore the "nationalization" of medical education and training. Medical school admission standards are similar across the country. Curricula are substantially the same. Internship and residency programs for those entering medical specialities have substantially common components. Nationally uniform standards are enforced in the case of certification of specialists. Differences and changes in these areas occur temporally, not geographically.

Physicians are far more mobile than they once were. They frequently attend medical school in one state, do a residency in another, establish a practice in a third and after a period of time relocate to a fourth. All

the while they have ready access to professional and scientific journals and seminars for continuing medical education from across the country. Common sense and experience inform us that the laws of medicine do not vary from state to state in anything like the manner our public law does.

King v. Murphy represents a recognition by this Court of what has long been an established fact: that the medical centers in Memphis, Birmingham, Mobile, New Orleans and other nearby areas in adjoining states are a very real part of the Mississippi-centered universe of hospitalization, medical care and treatment and other health related services.

Medicine is a science, though its practice be an art (as distinguished from a business). Regarding the basic matter of the learning, skill and competence a physician may bring to bear in the treatment of a given patient, state lines are largely irrelevant. That a patient's temperature is 105 degrees means the same in New York as in Mississippi. Bones break and heal in Washington the same as in Florida, in Minnesota the same as in Texas. An abnormal blood sugar count should be interpreted in California as in Illinois as in Tennessee. A patient's physiological response to an exploratory laparotomy and needs regarding post-operative care following such surgery do not vary from Ohio to Mississippi. A pulse rate of 140 per minute provides a danger signal in Pascagoula, Mississippi, the same as it does in Cleveland, Ohio. Bacteria, physiology and the life process itself know little of geography and nothing of political boundaries.

It is absurd to think that a physician examining a patient in his or her office would, by reference to the genuine health care needs of the patient, say: Because I practice in Mississippi (or the Deep South), I will make this diagnosis and prescribe this medication and course of treatment, but if I were in Iowa, I would do otherwise. We are confident (as the medical community of this state is no doubt confident) that Mississippi's physicians are capable of ren-

dering and do in fact render a quality of care on a par with that in other parts of the country.

- 3. The Competence-Based National Standard Of Care: Herein Of the Limited Role Of Local Custom
- [8,9] All of the above informs our understanding and articulation of the competence-based duty of care. Each physician may with reason and fairness be expected to possess or have reasonable access to such medical knowledge as is commonly possessed or reasonably available to minimally competent physicians in the same specialty or general field of practice throughout the United States, to have a realistic understanding of the limitations on his or her knowledge or competence, and, in general, to exercise minimally adequate medical judgment. Beyond that, each physician has a duty to have a practical working knowledge of the facilities, equipment, resources (including personnel in health related fields and their general level of knowledge and competence), and options (including what specialized services or facilities may be available in larger communities, e.g., Memphis, Birmingham, Jackson, New Orleans, etc.) reasonably available to him or her as well as the practical limitations on same.
- patient, each physician has a non-delegable duty to render professional services consistent with that objectively ascertained minimally acceptable level of competence he may be expected to apply given the qualifications and level of expertise he holds himself out as possessing and given the circumstances of the particular case. The professional services contemplated within this duty concern the entire caring process, including but not limited to examination, history, testing, diagnosis, course of treatment, medication, surgery, follow-up, after-care and the like.
- [11] Emphasis is given the proposition that physicians incur civil liability only when the quality of care they render falls below objectively ascertained minimally acceptable levels. Use of such concepts as

"average" are misleading and should be avoided, particularly in jury instructions, for such notions understood arithmetically suggest that the lower 50 percent of our physicians regularly engage in medical malpractice. We are confident that the percentage of physicians in this state who daily deliver to their patients a legally acceptable quality of care is quite high. The terminology we use, particularly in jury instructions, should reflect this reality.

[12] Mention should be made in this context of the role of good medical judgment which, because medicine is not an exact science, must be brought to bear in diagnostic and treatment decisions daily. Some physicians are more reluctant to recommend radical surgery than are other equally competent physicians. There exist legitimate differences of opinion regarding medications to be employed in particular contexts. "Waiting periods" and their duration are the subject of bona fide medical controversy. What diagnostic tests should be performed is a matter of particularly heated debate in this era of ever-escalating health care costs. We must be vigilant that liability never be imposed upon a physician for the mere exercise of a bona fide medical judgment which turns out, with the benefit of 20-20 hindsight, (a) to have been mistaken, and (b) to be contrary to what a qualified medical expert witness in the exercise of his good medical judgment would have done. We repeat: a physician may incur civil liability only when the quality of care he renders (including his judgment calls) falls below minimally acceptable levels.

Different medical judgments are made by physicians whose offices are across the street from one another. Comparable differences in medical judgment or opinion exist among physicians geographically separated by much greater distances, and in this sense local custom does and must continue to play a role within our law, albeit a limited one.

[13, 14] We recognize that customs vary within given medical communities and

from one medical community to another. Conformity with established medical custom practiced by minimally competent physicians in a given area, while evidence of performance of the duty of care, may never be conclusive of such compliance. Cf. Helling v. Carey, 83 Wash.2d 514, 519 P.2d 981 (1974). The content of the duty of care must be objectively determined by reference to the availability of medical and practical knowledge which would be brought to bear in the treatment of like or similar patients under like or similar circumstances by minimally competent physicians in the same field, given the facilities, resources and options available. The content of the duty of care may be informed by local medical custom but never subsumed by it.

Conformity with a local medical custom may be one factor suggesting that a physician has fulfilled his obligation of care. On the other hand, failure to conform to an established medical custom regarding care will generally lead inescapably to the conclusion that the duty of care has been breached.

#### 4. The Resources-Based Caveat to the National Standard of Care

The duty of care, as it thus emerges from considerations of reason and fairness, when applied to the facts of the world of medical science and practice, takes two forms: (a) a duty to render a quality of care consonant with the level of medical and practical knowledge the physician may reasonably be expected to possess and the medical judgment he may be expected to exercise, and (b) a duty based upon the adept use of such medical facilities, services, equipment and options as are reasonably available. With respect to this second form of the duty, we regard that there remains a core of validity to the premises of the old locality rule.

For reasons well known to all, the facilities, equipment, health care personnel, and other such resources reasonably available to Mississippi's physicians vary from community to community. Major differences exist between the tools the physician has to work within rural Mississippi as contrasted

with our more urban areas. Generally speaking, the most comprehensive availability of sophisticated medical facilities and equipment in this state may be found in Jackson.

Because of these differences in facilities, equipment, etc., what a physician may reasonably be expected to do in the treatment of a patient in rural Humphreys County or Greene County may vary from what a physician in Jackson may be able to do. A physician practicing in Noxubee County, for example, may hardly be faulted for failure to perform a CAT scan when the necessary facilities and equipment are not reasonably available. In contradistinction, objectively reasonable expectations regarding the physician's knowledge, skill, capacity for sound medical judgment and general competence are, consistent with his field of practice and the facts and circumstances in which the patient may be found, the same everywhere.

One of the cases which started the present trend toward judicial abolition of the old locality rule, *Pederson v. Dumouchel*, 72 Wash.2d 73, 431 P.2d 973 (1967), perceived that the quality of care a physician was obligated to render should be consistent

with the medical and professional means available in those centers that are readily accessible for appropriate treatment of the patient.

431 P.2d at 978 (emphasis added).

Another such case, Brune v. Belinkoff, 354 Mass. 102, 235 N.E.2d 793 (1968), similarly permits consideration of "the medical resources available to the physician". 235 N.E.2d at 798.

Justice Hawkins spoke closer to home in his separate opinion in *King*:

... [S]mall town practitioners whose daily practice requires them to treat patients in what might be deemed less than ideal circumstances should not be penalized or obligated to ... utilize the same equipment of a medical specialist in a metropolitan hospital.

424 So.2d at 551 n. 1.

component, the physician's non-delegable duty of care is this: given the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence, and prudence as are practiced by minimally competent physicians in the same specialty or general field of practice throughout the United States, who have available to them the same general facilities, services, equipment and options.

#### 5. King v. Murphy Revisited

When all that has been said above is considered, we today do little more than smooth some of the rough edges of King v. Murphy. King recognizes that, as a part of our law, the formulation of the duty of care is to be informed by standards of medical competence prevailing statewide in Mississippi "and for a reasonable distance adjacent to state boundaries". 424 So.2d at 550. This necessarily includes Memphis, Mobile and New Orleans at the very least. When the standards of medical practice prevailing in Jackson, Mississippi, are added, it may be seen that for all practical purposes King has embraced what many call the "national standard of care". Aside from highly specialized and in many instances still experimental services with respect to certain catastrophic diseases and medical problems, the quality of medical and health care in Memphis, Mobile, New Orleans and Jackson is consistent with that available anywhere in the land. The refinement of King we make on this score may be expected to eliminate legalistic debates over whether Birmingham, or Houston, or Nashville, or Atlanta is within "a reasonable distance adjacent to state boundaries". Past that it should have little practical effect.

On the other hand, we have added to King a pragmatic addendum by today's

 To the extent they may announce or proceed on the assumption of the existence of rules of law in conflict with those set forth here, King v. Murphy, Holmes v. Elliott, 443 So.2d 825 (Miss. recognition that the physician's duty of care must take into consideration the quality and kind of facilities, services, equipment and other resources available. Nothing in *King* precluded consideration of this factor, which in reason and fairness ought to be a part of our law's approach to medical malpractice cases. Today we remove all doubt of the matter.

[16] As we deal with general principles. gray areas necessarily exist. One involves the case where needed specialized facilities and equipment are not available locally but are reasonably accessible in major medical centers-New Orleans, Jackson, Memphis. Here as elsewhere the local physician is held to minimally acceptable standards. In determining whether the physician's actions comport with his duty of care, consideration must always be given to the time factor-is the physician confronted with what reasonably appears to be a medical emergency, or does it appear likely that the patient may be transferred to an appropriate medical center without substantial risk to the health or life of the patient? Consideration must also be given to the economic factors—are the proposed transferee facilities sufficiently superior to justify the trouble and expense of transfer? Further discussion of these factors should await proper cases.

#### D. Who May Qualify As Expert Medical Witness In Malpractice Case: A rule of evidence

[17] As a general rule, if scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education (or a combination thereof), coupled with independence and lack of bias, may testify thereto in the form of an opinion or

1983), and all of our other prior medical malpractice cases shall from and after this day stand modified or overruled as may be appropriate. otherwise.<sup>8</sup> Medical malpractice cases generally require expert witnesses to assist the trier of fact to understand the evidence. *Kilpatrick v. Mississippi Baptist Medical Center*, 461 So.2d 765, 768 (Miss.1984).

[18] Generally, where the expert lives or where he or she practices his or her profession has no relevance per se with respect to whether a person may be qualified and accepted by the court as an expert witness. There is no reason on principle why these factors should have per se relevance in medical malpractice cases. This is the clear meaning of King v. Murphy wherein Justice Roy Noble Lee, speaking for the Court, wrote:

An expert witness ... shall not have his testimony excluded on the ground that he does not practice in this state.

424 So.2d at 550.

While the language of King is as clear as it can be, we are aware of two misinterpretations which have been given it among the bench and bar. First, some have read King as merely enlarging the pool of available medical expert witnesses to include those who geographically reside in areas adjacent to Mississippi. Physicians from Boston or Chicago or San Francisco would still be excluded as a matter of law. The place of professional residence of the expert, however, is of no relevance at all under King, so long as it is in this country. That the expert may hail from Oregon or Massachusetts or from Cleveland, Ohio, has no per se relevance.

Second, some have read King as requiring that the expert possess intimate knowledge of how things are done in the particular Mississippi medical facility in issue. King, however, expressly rejects the notion that a particular medical community or facility could by custom or agreement establish the standards by which a patient's malpractice action should be adjudged. King recognizes that in the area of medical knowledge, skill and competence there is a common minimally acceptable standard

8. What we say here is consistent with Rule 702 of the proposed Mississippi Rules of Evidence, petitions for adoption of which are presently

throughout a neighborhood or locality geographically defined as including this state and "for a reasonable distance adjacent to state boundaries." 424 So.2d at 550. The source of this standard (as refined in Subsection III(C) above) and the duty based upon it (as elaborated in Subsection III(C) above) is the positive law of the state, not medical custom. It is that minimum legal standard (to be sure, informed by customs) with which the expert must be familiar, yet we know that some lawyers argue and some trial judges read *King* quite differently.

What is really at issue here is whether we will treat medical expert witnesses the same as experts in other fields. The old locality rule and the misreading some have given King would add a geographical component. Though we regard the majority opinion in King as having clearly stated the rule, we are indebted to Justice Hawkins for reminding us persistently that there is no valid basis in judicial reason for not treating

the question of the competency of the testimony of physicians the same as any other expert.

Holmes v. Elliott, 443 So.2d 825, 833 (Miss.1983) (Hawkins, J., specially concurring)

[19, 20] In view of the refinements in the physician's duty of care articulated in Subsection III(C) above, we hold that a qualified medical expert witness may without more express an opinion regarding the meaning and import of the duty of care articulated in Subsection III(C) above, given the peculiar circumstances of the case. Based on the information reasonably available to the physician, i.e., symptoms, history, test results, results of the doctor's own physical examination, x-rays, vital signs, etc., a qualified medical expert may express an opinion regarding the conclusions (possible diagnoses or areas for further examination and testing) minimally know-

pending before the Court. See also, House v. State, 445 So.2d 815, 822 (Miss.1984).

ledgeable and competent physicians in the same specialty or general field of practice would draw, or actions (not tied to the

would draw, or actions (not tied to the availability of specialized facilities or equipment not generally available) they would take.

[21] Before the witness may go further, he must be familiarized with the facilities, resources, services and options available. This may be done in any number of ways. The witness may prior to trial have visited the facilities, etc. He may have sat in the courtroom and listened as other witnesses described the facilities. He may have known and over the years interacted with physicians in the area. There are no doubt many other ways in which this could be done, but, significantly, we should allow the witness to be made familiar with the facilities (and customs) of the medical community in question via a properly predicated and phrased hypothetical question.

Once he has become informed of the facilities, etc. available to the defendant physician, the qualified medical expert witness may express an opinion what the care duty of the defendant physician was <sup>10</sup> and whether the acts or omissions of the defendant physician were in compliance with, or fell substantially short of compliance with, that duty.

At this point it is appropriate to note the earnestness with which counsel for Dr. Hilbun, no doubt purporting to speak on behalf of the medical community generally, begs for protection from the circuit-riding charlatan, the man from out of town with a briefcase. The instrument with which they would have us afford this protection is too blunt. Justice Hawkins in this context has aptly observed:

It seems incongruous to me that a medical specialist from the Mayo Clinic, the Ochsner Clinic, the Menninger Founda-

- Anything to the contrary which may be found in King v. Murphy, Holmes v. Elliott, or any of our other prior medical malpractice cases shall stand authoritatively modified by what we say here. See supra Note 7.
- 10. The duty "was" what it "reasonably should have been"—see the point regarding the non-

tion, or the Sloan-Kettering Institute could not express opinions within his field of knowledge on what constitutes good medical practice in any court in the United States, or on this entire planet, for that matter.

King v. Murphy, 424 So.2d 547, 552 (Miss.1982) (Hawkins, J., dissenting)

We remind one and all that qualification of a medical expert witness in a malpractice action is no more a mechanical process than any other procedure in our law. Within the limits of the general rule stated above, the trial judge is necessarily called upon to exercise his sound discretion in determining whether a proffered witness is in fact qualified as an expert. See Pharr v. Anderson, 436 So.2d 1357, 1359 (Miss. 1983).

[22] Our trial judges are admonished to ascertain that the witness really is an expert in the particular field at issue. Not every M.D. is a qualified expert in every malpractice case. Liberal cross-examination regarding bias, interest and previous experience as an expert in medical malpractice cases should be allowed both on voir dire and when the witness' testimony is being presented to the jury.

#### IV. The Rules We Announce Apply Retroactively

[23] It is a general rule that judicially enunciated rules of law are applied retroactively. Legislation applies prospectively only, and we are not thought to be in the business of legislating. Rather, our function is to decide cases justly in accordance with sound legal principles which of necessity must be formulated, articulated and applied consistent with the facts of the case.

controlling effect of local medical custom or practice stated above in subsection III(c)(3) on pages 875 and 876.

 Counsel noticeably eschews application of these epithets to the two proffered experts in the case at bar, Drs. Hoerr and Sachs. Keyes v. Guy Bailey Homes, Inc., 439 So.2d 670 (Miss.1983), abolishing the requirement of privity of contract in home construction contracts applied retroactively; Tideway Oil Programs, Inc. v. Serio, 431 So.2d 454 (Miss.1983), providing that punitive damages may be recovered in chancery court was applied retroactively; McDaniel v. State, 356 So.2d 1151 (Miss. 1978) overruling cases which allowed voluntary intoxication as a defense to a crime applied retroactively.

The general rule applied universally in this country in federal and state courts is simply put in *Jones v. Thigpen*, 741 F.2d 805 (5th Cir.1984).

"Judicial decisions ordinarily apply retroactively. See Robinson v. Neil, 409 U.S. 505, 507–08, 93 S.Ct. 876, 877–78, 35 L.Ed.2d 29 (1973). 'Indeed, a legal system based on precedent has a built-in presumption of retroactivity. Solem v. Stumes, — U.S. —, —, 104 S.Ct. 1338, 1341, 79 L.Ed.2d 579 (1984)." —741 F.2d at 810.

Even *Pruett v. City of Rosedale*, 421 So.2d 1046 (Miss.1982), was held to apply retroactively to that case.

We note that other states, when shedding the "locality rule", have done so in a routine manner by simply adopting the new rule and applying it in a normal (retroactive) fashion without fanfare. See Zills v. Brown, 382 So.2d 528, 532 (Ala.1980) applying this new rule retroactively in Drs. Lane, Bryant, Eubanks & Dulaney v. Otts, 412 So.2d 254, 256-8 (Ala.1982) and May v. Moore, 424 So.2d 596, 597-601 (Ala. 1982); Jenkins v. Parrish, 627 P.2d 533, 537 n. 1 (Utah 1981) (rule to be applied retroactively); Orcutt v. Miller, 95 Nev. 408, 595 P.2d 1191, 1194-95 (1979) (new rule routinely applied); Ardoin v. Hartford Accident & Indemnity Co., 360 So.2d 1331. 1339 n. 22 (La.1978) (overruling Percle v. St. Paul Fire & Marine Insurance Co., 349 So.2d 1289, 1303 (La.Ct.App.1977), which had held abandonment of locality

12. Alaska also has not applied a new standard of care retroactively, but that is because the standard was legislatively enacted by statute

rule to be prospective only); Bruni v. Tatsumi, 46 Ohio St.2d 127, 134-35, 346 N.E.2d 673, 679 (1976) (new rule routinely applied); Kronke v. Danielson, 108 Ariz. 400, 403, 499 P.2d 156, 159 (1972) (same); Wiggins v. Piver, 276 N.C. 134, 141, 171 S.E.2d 393, 397-98 (1970) (same); Naccarato v. Grob, 384 Mich. 248, 253-54, 180 N.W.2d 788, 791 (1970) (same); Brune v. Belinkoff, 354 Mass. 102, 108-09, 235 N.E.2d 793, 798 (1968) (same). Even when acknowledging the issue to be one of first impression, one court applied the new rule routinely with no hint of prospective-only application. Morrison v. MacNamara, 407 A.2d 555, 562 (D.C.1979).

The only case <sup>12</sup> we have found in which a court chose to make the abolition of the "locality rule" prospective only is *Shier v. Freedman*, 58 Wis.2d 269, 283 n. 2, 206 N.W.2d 166, 174 n. 2 (1973). See also, *Cukrowski v. Mount Sinai Hospital, Inc.*, 67 Wis.2d 487, 501–02, 227 N.W.2d 95, 102–03 (1975). The merit in the Wisconsin approach is not apparent.

[24] The retroactivity question with reference to the evidentiary rule-who may qualify as an expert witness—is easy. Physicians no less than others do not engage in primary private activity in reliance on rules of evidence. The refinement we place today on King v. Murphy should be applied in the trial of this case on remand. In any case in which an appeal is pending and in which the issue has been properly preserved, the evidentiary rule announced in King and refined today must be applied. In some instances, we recognize that this will necessitate a new trial. Finally, the rule applies to all cases tried after this date (including, of course, cases where the operative events giving rise to the plaintiff's claim arose prior to this date). The rule may not be applied, however, to disturb judgments which on or prior to this date have become final.

The retroactivity vel non of the rule regarding the physician's duty of care is

which expressly announced the date said statute was to be effective. *Priest v. Lindig,* 583 P.2d 173, 177 n. 13 (Alaska 1978).

arguably more difficult. Injustice would necessarily attend our passing judgment on the conduct of a citizen by reference to substantive rules substantially different from those in effect and relied upon by the citizen at the time of his conduct. We recognize that

the confidence of people in their ability to predict the legal consequences of their actions is vitally necessary to facilitate the planning of primary activity....

Moragne v. States Marine Lines, Inc., 398 U.S. 375, 403, 90 S.Ct. 1772, 1789, [26] L.Ed.2d 339, 358 (1970), quoted in Tideway Oil Programs, Inc. v. Serio, 431 So.2d 454, 465 (Miss.1983).

These fundamental premises have more validity in contracts, property and other business or economic contexts than in tort cases. Still, if it could be demonstrated that at the time Dr. Hilbun prescribed the regimen of post-operative care for Mrs. Hall he acted in reliance upon the validity of standards substantially more favorable to him than those we state today, that would weigh heavily in support of non-retroactivity. We do not perceive this to be the case.

[25] What we say today with regard to the standard of care amounts to little more than the law catching up with the way physicians have practiced their profession for years. Moreover, today's decision was "clearly foreshadowed" by the dictum in Dazet v. Bass, and by King v. Murphy. See Chevron Oil Co. v. Huson, 404 U.S. 97, 106, 92 S.Ct. 349, 30 L.Ed.2d 296, 306 (1971) (foreshadowing removes potential for injustice). We today do little more than fulfill

13. King v. Murphy was decided November 17, 1982. Petition for rehearing was denied January 14, 1983. 424 So.2d 547. Pharr v. Anderson, 436 So.2d 1357 (Miss.1983), arose out of events occurring on January 23-24, 1979. Language in the opinion suggests that the King rule was "consulted" to determine the competence of the testimony of a medical expert. 436 So.2d at 1359. Holmes v. Elliott, 443 So.2d 825 (Miss. 1983), arose out of events occurring in September of 1977. King v. Murphy was applied to exclude the testimony of an expert medical witness from Oklahoma City, Oklahoma. It is true that Reikes v. Martin, No. 53,915, decided on

the prophecy of *Dazet* and smooth some of *King's* rough edges. Seen in this context, retroactivity works no unfairness. Conversely, substantial unfairness to Plaintiff Hall would attend our refusal to allow a new trial to be conducted under the rules articulated above.<sup>13</sup>

#### V. Disposition Of The Case At Bar

Our task now becomes the reasoned application of these rules of law and their elaboration to the facts—and the procedural posture—of the case at bar.

Beginning with the substantive duty, we recognize that Dr. Hilbun was obligated to Terry O. Hall to exercise that degree of skill and care which a minimally competent surgeon would have exercised in the same or similar circumstances. Without question, Dr. Hilbun performed the surgery, i.e., the exploratory laporatomy, skillfully and successfully. He remained with Mrs. Hall in the recovery room from 1:35 p.m. until approximately 2:50 p.m. at which time she was alert, communicative, and her vital signs were stable. The problems arise thereafter.

[26] In the first place, we are confident that the first 24 hours post-surgery for any patient present matters within the common knowledge of any surgeon. Subject to variation with the patient's age, history and general state of health prior to surgery, there are surely a number of commonly known and reasonably to be anticipated complications and danger signals common to all post-operative patients.<sup>14</sup> These are matters that surgeons such as Dr. Hilbun are expected to know. More importantly,

January 25, 1984, states that King v. Murphy shall be applied prospectively only. Reikes is pending before this Court on petition for rehearing. Consistent with the implications of Pharr, the holding of Holmes, and what we have said above, the statement in Reikes is seen as incorrect.

14. On retrial it should be developed more fully whether and to what extent a 140 pulse rate and adult respiratory distress syndrome are "commonly known and reasonably to be anticipated complications". they are matters with respect to which surgeons such as Dr. Hilbun have a duty of care to their patients.

[27] Dr. Hilbun held himself out to the public in general and to Terry O. Hall in particular as being competent to perform the surgery in question. He thereby acquired an obligation to Mrs. Hall to perform all facets of the surgery with that level of competence and diligence as might be expected of minimally competent surgeons under the circumstances. The relevant circumstances include those of the particular patient, any objectively sound local medical custom, and the facilities, resources and options available as discussed in Section III(C)(4) above. He particularly became obligated to direct the post-operative care of Mrs. Hall and to ensure that, with respect to all post-operative dangers or complications reasonably to be anticipated under the circumstances, adequate provision was made for prompt diagnosis and treatment.

A central question of law presented on this appeal is whether there was sufficient evidence presented to the court to undergird a jury finding that Dr. Hilbun had breached this duty owed to Mrs. Hall. Evidentiary sufficiency in this context, of course, is governed by our familiar standards as described in Paymaster Oil Mill Co. v. Mitchell, 319 So.2d 652, 657 (Miss. 1975), and numerous progeny, particularly including, sub silentio, Pharr v. Anderson, 436 So.2d 1357, 1361 (Miss.1983). sidering only the proof admitted at trial, we are forced to agree that the evidence was insufficient as a matter of law and that Dr. Hilbun was entitled to a directed verdict.

As indicated above, Plaintiff Hall sought to overcome this predicament by calling as expert witnesses Drs. Hoerr and Sachs. Our outcome-determinative question, therefore, turns on whether the trial court correctly ruled, as a matter of the law of evidence, that these two witnesses could not, consistent with our law of evidence, testify as expert witnesses.

[28] In view of what we have said in Section III(D) above, it was error to exclude the testimony of these two witnesses in its entirety. Each was clearly competent to testify regarding matters related to the level of knowledge, skill, medical judgment and general competence a surgeon should have brought to bear in prescribing and administering the post-operative regimen for a patient such as Mrs. Hall.

[29] Dr. Hilbun makes much of the fact that his own expert witness, Dr. Donald Dohn, until recently also of Cleveland, Ohio, testified regarding the differences between practice in the Singing River Hospital and in Cleveland, Ohio. Our careful review of the testimony of Dr. Dohn fails to reveal any objectively reasonable basis for concluding that there is a difference in the regimen of post-operative care a minimally competent surgeon should have prescribed for a patient such as Mrs. Hall by reference to her genuine health care needs. The differences discussed by Dr. Dohn relate to differences in medical facilities, services and resources available to the practicing physician-no doubt those resources are greater in Cleveland, Ohio, than in Pascagoula, Mississippi. There is no basis for believing that any of these differences, however, would have resulted in any qualitative difference in the regimen of post-operative care prescribed. Put another way, a 37 year old woman such as Mrs. Hall may be expected to respond to an exploratory laporatomy the same whether she receives her surgery and post-operative care in Cleveland, Ohio, or Pascagoula, Mississippi.

Insofar as the record reflects, the only possible basis for Dr. Hilbun's contention that there are relevant differences between Cleveland, Ohio, and Pascagoula, Mississippi, regards the general quality and competence of nursing personnel. Dr. Hilbun has been less than complimentary of the nursing staff at Singing River Hospital. The record reflects that Dr. Hilbun had been practicing in the Singing River Hospital for approximately 16 years and that he was thoroughly familiar with the capabili-

Cite as 466 So.2d 856 (Miss. 1985)

ties of the nursing staff, and the limitations thereon.

[30-33] By establishing the inadequacy of the nursing and personnel resources available to him in Pascagoula, Mississippi, Dr. Hilbun only increases his own responsibility. Where a physician is working with medical personnel of known modest competence, his duty of instruction and control is increased. That Dr. Hilbun may have had doubts about the quality of nursing care at the Singing River Hospital lends considerable credibility to the expert testimony of Dr. Hoerr to the effect that far more specific post-operative orders or instructions should have been provided in the case of Mrs. Hall.

Without further ado, and applying to the facts of this case the legal principles stated above, we hold as follows: to the extent that the testimony of Drs. Hoerr and Sachs was excluded because these two physicians lived and had their practices in Cleveland, Ohio, the trial court erred. To the extent that the testimony of each of these physicians was excluded in its entirety because they were supposedly not familiar with the standard of care in Pascagoula, Mississippi, in general or in the Singing River Hospital in particular, the trial court erred.

Without the testimony of Drs. Hoerr and Sachs, Plaintiff Hall has no case. With that testimony, Plaintiff Hall has a fighting chance to survive a motion for a directed verdict. We say this because the trial judge, when he considered and granted defendant's motion for a directed verdict, was proceeding without reference to the testimony of Drs. Hoerr and Sachs which had

15. The limited record before us suggests that the nurses charged with attending Mrs. Hall on the early morning hours of May 21, 1978, were grossly negligent. They were sued originally as "X, Y, and Z, Unknown Nurses". Although the names of these nurses were produced in answers to interrogatories, plaintiff inexplicably never amended to name them formally or have them served with process.

Again, on this limited record, it appears that Dr. Hilbun's failures in the area of post-operative care were not so substantial as the nurses' failures. Under established law, however, if Dr. Hilbun breached the duty of care he owed to

been excluded. The core holding of today's decision is that the trial judge erred when he directed a verdict for defendant without taking into account the testimony of plaintiff's two out of state experts. That error was prejudicial because the testimony of Drs. Hoerr and Sachs does suggest a basis on which reasonable minds might determine that Dr. Hilbun breached the duty of care he owed to Terry O. Hall. The judgment below is reversed, and this case is remanded for a new trial.

At the new trial, if Plaintiff Hall wishes to call either Dr. Hoerr or Dr. Sachs, each may be permitted to testify and be crossexamined consistent with the legal principles stated in Sections III and IV above. More specifically and without limitation, each may describe and elaborate upon such medical knowledge as is commonly possessed or is reasonably available to minimally competent surgeons throughout the country. Each may be permitted to express an opinion as to whether the quality of post-operative care rendered Mrs. Hall by Dr. Hilbun conformed to objectively ascertained minimally acceptable levels. In expressing such an opinion, each should consider such legitimate differences of opinion as may exist within the medical profession regarding the regimen of postoperative care that ought to have been provided a patient such as Mrs. Hall. Further, to the extent that, in order to express such an opinion, consideration need be given to the facilities, equipment, personnel and general medical resources available, Drs. Hoerr and Sachs must be fully apprised of and required to assume these prior to answering.

Mrs. Hall and if such breach, if any, was a proximate cause of Mrs. Hall's death, plaintiff may recover full damages of and from Dr. Hilbun, notwithstanding that others may have been more at fault and that their fault was the more substantial factor causing Mrs. Hall's death. This case falls within the settled rule that joint tortfeasors are jointly and severally liable to the plaintiff who, at his election, may sue fewer than all and recover full damages from those sued. See Campbell v. Schmidt, 195 So.2d 87, 89–90 (Miss.1967); Bailey v. Delta Electric Light, Power and Manufacturing Co., 86 Miss. 634, 636, 38 So. 354 (1905).

Nothing said here should be taken as an expression of opinion on our part that Dr. Hilbun has committed malpractice. All that today's decision suggests on this point is that, with the expert testimony of Drs. Hoerr and Sachs added to his case, plaintiff may be able to present a jury question; that is, plaintiff may on retrial be able to make out a case so that, when the evidence and all reasonable inferences therefrom are viewed in the light most favorable to him, the trial judge may be unable to say that no reasonable juror could find for him.

The trial judge is not by today's decision required to deny defendant's motion for a directed verdict made at the end of plaintiff's case on retrial. Rather, that motion should be considered in the light of the evidence then before the court, measured by the substantive standards articulated in Sections III(c)(3) and (4) above, and viewed favorably to plaintiff under our familiar rules. See Paymaster Oil Mill Co. v. Mitchell, 319 So.2d 652, 657 (Miss.1975); Pharr v. Anderson, 436 So.2d 1357, 1361 (Miss.1983). When this is done, we are confident reason and fairness will mark the outcome.

PETITION FOR REHEARING GRANT-ED; REVERSED AND REMANDED FOR A NEW TRIAL.

DAN M. LEE, PRATHER, SULLIVAN and ANDERSON, JJ., concur.

HAWKINS, J., specially concurs.

PATTERSON, C.J., and ROY NOBLE LEE, P.J., concur in part and dissent in part.

WALKER, P.J., dissents.

HAWKINS, Justice, specially concurring:

I concur in the decision reached by the majority.

I am grateful to Justice Robertson for his recitation of the facts, as well as the abundant authorities he has furnished on the locality rule.

Thanks should also be expressed for the graveside eulogy he has delivered to *King v. Murphy*, 424 So.2d 547 (Miss.1982).

Hopefully, the Bench and Bar now has the indubitably clear expression of what I attempted to state in the King v. Murphy dissent.

PATTERSON, Chief Justice, dissenting in part; concurring in part:

I was the author of the original opinion in this cause and concluded the trial court correctly followed our rule of evidence established in Dazet v. Bass, 254 So.2d 183 (Miss.1971). Therefore, believing the court had not committed error by following precedent, I thought an affirmance was in order. It would appear from the record, however, that the procedures followed, although correct, possibly led to an unusual result in that a full trial on the merits did not follow. It also appears, to me at least, that although authorized by our procedures the dismissal of Nurses XYZ from the suit by the plaintiff left the defendant doctor the prime target for liability and thus damages when from the record before us his negligence, if any, was slight by comparison to that of Nurses XYZ. To explain, it need be recalled that despite great fluctuation of the patients's vital signs, the doctor was simply not notified of such until called the next morning at the insistence of the patient's husband. He promptly responded but unfortunately at a time too late to save his patient.

I dissent because I think the trial judge and the attorneys were entitled to rely on our law as it existed, through precedent, at the time of the trial.

Presently in the minority, I concur with the majority that the locality rule of evidence in malpractice cases should be overturned. The rule was greatly expanded in King v. Murphy, 424 So.2d 547 (Miss.1982). I would now forthrightly hold that we adopt the National Standard of Evidence which permits a medical expert to testify once his qualifications have been established, just as other expert witnesses are presently qualified to give testimony.

WALKER, P.J., joins the dissenting part.

## Pennsylvania Suggested Standard Civil Jury Instructions Third Edition Volume II Chapter XI - Medical Professional Negligence Current through April 2010

#### 11.04 (CIV) DIFFERING SCHOOLS OF THOUGHT DOCTRINE

Where competent medical authority is divided, a physician will not be held responsible if, in using his or her judgment, the physician followed a course of treatment advocated by a considerable number of recognized and respected professionals in his or her given area of expertise. This is known as the "two schools of thought" doctrine.

The defendant claims that, in treating the plaintiff, [he] [she] consciously chose to follow a course of treatment. The defendant has the burden of proving, by a fair preponderance of the evidence, that a considerable number of recognized and respected professionals advocated the same course of treatment, that [he] [she] was aware of these professionals advocating this same course of treatment at the time [he] [she] treated the plaintiff, and that in treating the plaintiff [he] [she] consciously chose to follow their recommended course of treatment. If you determine that the defendant has met this burden of proof, then you should find for the defendant.

These instructions apply only to the plaintiff's claim that [identify applicable theory of liability]. The plaintiff also contends that the defendant was negligent in [identify remaining theories of liability]. The "two schools of thought" doctrine has no application to [this other claim] [these other claims] and you may not consider the doctrine regarding [this other claim] [these other claims].

#### SUBCOMMITTEE NOTE

The "two schools of thought" doctrine in medical malpractice cases was first recognized in Pennsylvania in *Remley v. Plummer*, 79 Pa.Super. 117 (1922). The jury must be made to realize, in appropriate cases, that the practitioner may properly choose to act in accordance with a minority viewpoint, if that viewpoint is not one of an insignificant minority and is reputable. *Donaldson v. Maffucci*, 156 A.2d 835 (Pa. 1959); *Tobash v. Jones*, 213 A.2d 588 (Pa. 1965). The course of treatment must be one advocated by a considerable number of the physicians' brethren, *Duckworth v. Bennett*, 181 A. 558, 559 (Pa. 1935). A "small respected body" of medical practitioners believing in an optional procedure is not sufficient to trigger the application of the *Duckworth* standard. *Brannan v. Lankenau Hosp.*, 417 A.2d 196 (Pa. 1980).

In <u>Trent v. Trotman</u>, 508 A.2d 580 (Pa.Super. 1986), the court approved an instruction almost verbatim with the instant instruction. In <u>Furey v. Thomas Jefferson University Hospital</u>, 472 A.2d 1083 (Pa.Super. 1984), the court found prejudicial error in the trial court's failure to give a submitted point for charge on the two schools of thought doctrine.

In <u>Morganstein v. House</u>, 547 A.2d 1180 (Pa.Super. 1988), the Superior Court noted that it was improper to charge the jury on the differing schools of thought doctrine where the question was whether the physician properly diagnosed the plaintiff's condition.

A significant, although subtle, point is the fact that although medical experts have testified in support of defendant-physicians' treatment, it does not prove that the treatment was in accordance with some accepted schools of thought. D'Angelis v. Zakuto, 556 A.2d 431 (Pa.Super. 1989). D'Angelis and Morganstein made it clear that this doctrine refers to issues concerning the propriety of treatment, not whether failure to make a diagnosis was negligent. (As our Supreme Court stated in Jones v. Chidester, 610 A.2d 964, 965 (Pa. 1992), the doctrine "is applicable only where there is more than one method of accepted treatment" for a patient's agreed-upon diagnosis. (Emphasis added.) See also Sinclair by Sinclair v. Block, 633 A.2d 1137, 1142 (Pa. 1993) (where there was no evidence of "two schools of thought" on the issue of whether defendant breached the standard of care in the actual application of forceps during attempted delivery, "[t]he issue is a credibility determination. Either the jury believed the [plaintiffs'] expert or [defendant's] expert. As a result, the 'two schools of thought' instruction was inappropriate for [this] claim of negligence.").

Where competent medical authority is divided, a physician will not be held responsible if, in the exercise of the physician's judgment, he or she followed a course of treatment "advocated by a considerable number of recognized and respected professionals in his given area of expertise." *Jones v. Chidester*. The burden of proving that there are two schools of thought falls to the defendant, but that burden should not be burdensome. "The proper use of expert witnesses should supply the answers." Id. Once the expert states the factual reasons to support his or her claim that there is a considerable number of recognized and respected professionals who agree with the treatment used by the defendant, there is sufficient evidence to warrant an instruction to the jury on the two "schools of thought." Id. Competent evidence that the requisite considerable number of recognized and respected professionals do agree with the allegedly negligent treatment need not be in the form of medical literature, but may be established by expert testimony. Gala v. Hamilton, 715 A.2d 1108 (Pa. 1998). Of course, the reference to a physician's judgment in this instruction rests on the premise that "competent medical authority is divided." See also Jones v. Chidester; Duckworth v. Bennett. Given that the doctrine constitutes a complete defense to a plaintiff's claim, this point bears emphasis. It is axiomatic that, absent the predicates to make this defense available, an "exercise of judgment" cannot insulate a defendant from liability; thus, no reference should be made, in such circumstances, to a physician's exercise of judgment in choosing a particular course of treatment.

Where the two schools of thought doctrine applies, the trial judge must specify on which allegation of negligence there were two schools of thought. "The two schools of thought doctrine does not relieve a doctor from liability for failure to recognize symptoms of an illness." *Levine v. Rosen*, 616 A.2d 623, 628 (Pa. 1992). Another case came to the same conclusion: in charging a jury on the doctrine, the trial judge must specify on which allegation of negligence the two schools of thought doctrine applies. *Sinclair v. Block*, 633 A.2d 1137, 1141 (Pa. 1993). See also *Rittenhouse v. Hanks*, 777 A.2d 1115, 1118 (2001) ("two schools of thought" doctrine was inapplicable, and jury instruction thereon would have been inappropriate, with regard to treatment other than that which plaintiff claimed was negligent). See also *Choma v. Iyer*, 871 A.2d 238 (Pa.Super. 2005).



83 Wash.2d 514, 519 P.2d 981, 67 A.L.R.3d 175

(Cite as: 83 Wash.2d 514, 519 P.2d 981)

Supreme Court of Washington, En Banc. Morrison P. HELLING and Barbara Helling, his wife, Petitioners,

Thomas F. CAREY and Robert C. Laughlin, Respondents.

No. 42775.

March 14, 1974.

Malpractice action against ophthalmologists in which a patient claimed that she suffered permanent visual damage due to open angle glaucoma as a result of defendants' failure to diagnose and treat the condition. The trial court entered judgment for defendants following a defense verdict, the Court of Appeals, Division I, James, J., affirmed, and the patient petitioned for review. The Supreme Court, Hunter, J., held that defendants were negligent as a matter of law in failing to administer a simple glaucoma test to the patient despite uncontradicted expert testimony that it was the universal practice of ophthalmologists not to administer glaucoma tests to patients under age 40 because the incidence of glaucoma at younger ages was so small.

Reversed and remanded for new trial on issue of damages only.

Utter, J., concurred and filed opinion in which Finley and Hamilton, JJ., concurred.

#### West Headnotes

#### Health 198H € 2670

198H Health

198HV Malpractice, Negligence, or Breach of Duty

198HV(C) Particular Procedures 198Hk670 k. Eyes. Most Cited Cases (Formerly 299k18.80(8) Physicians and Surgeons)

Ophthalmologists were negligent as matter of law in failing to administer glaucoma test to patient under age 40, thus failing to diagnose condition of primary open angle glaucoma, despite uncontradicted expert testimony that it was universal practice of ophthalmologists not to test patients younger than 40 for glaucoma because of low incidence of condition in younger patients.

\*515 \*\*981 Olwell, Boyle & Hattrup, Lee Olwell, Seattle, for petitioner.

Williams, Lanza, Kastner & Gibbs, Henry E. Kastner, Seattle, for respondent.

HUNTER, Associate Justice.

This case arises from a malpractice action instituted by the plaintiff (petitioner), Barbara Helling.

The plaintiff suffers from primary open angle glaucoma. Primary open angle glaucoma is essentially a condition of the eye in which there is an interference in the ease with which the nourishing fluids can flow out of the eye. Such a condition results in pressure gradually rising above the normal level to such an extent that damage is produced to the optic nerve and its fibers with resultant loss in vision. The first loss usually occurs in the periphery of the field of vision. The disease usually has few symptoms and, in the absence of a pressure test, is often undetected until the damage has become extensive and irreversible.

The defendants (respondents), Dr. Thomas F. Carey and Dr. Robert C. Laughlin, are partners who practice the medical specialty of ophthalmology. Ophthalmology involves the diagnosis and treatment of defects and diseases of the eye.

The plaintiff first consulted the defendants for myopia, nearsightedness, in 1959. At that time she was fitted with contact lenses. She next consulted the defendants in September,\*516 1963, concerning irritation caused by the contact lenses. Additional (Cite as: 83 Wash.2d 514, 519 P.2d 981)

consultations occurred in October, 1963; February, 1967; September, 1967; October, 1967; May, 1968; July, 1968; August, 1968; September, 1968; and October, 1968. Until the October 1968 consultation, the defendants considered the plaintiff's visual problems to be related solely to complications associated with her contact lenses. On that occasion, the defendant, Dr. Carey, tested the plaintiff's eye pressure and field of vision for the first time. This test indicated that the plaintiff had glaucoma. \*\*982 The plaintiff, who was then 32 years of age, had essentially lost her peripheral vision and her central vision was reduced to approximately 5 degrees vertical by 10 degrees horizontal.

Thereafter, in August of 1969, after consulting other physicians, the plaintiff filed a complaint against the defendants alleging, among other things, that she sustained severe and permanent damage to her eyes as a proximate result of the defendants' negligence. During trial, the testimony of the medical experts for both the plaintiff and the defendants established that the standards of the profession for that specialty in the same or similar circumstances do not require routine pressure tests for glaucoma upon patients under 40 years of age. The reason the pressure test for glaucoma is not given as a regular practice to patients under the age of 40 is that the disease rarely occurs in this age group. Testimony indicated, however, that the standards of the profession do require pressure tests if the patient's complaints and symptoms reveal to the physician that glaucoma should be suspected.

The trial court entered judgment for the defendants following a defense verdict. The plaintiff thereupon appealed to the Court of Appeals, which affirmed the judgment of the trial court. Helling v. Carey, No. 1185-41918-1 (Wn.App., filed Feb. 5, 1973). The plaintiff then petitioned this Court for review, which we granted.

In her petition for review, the plaintiff's primary contention is that under the facts of this case the trial judge erred in giving certain instructions to the jury and refusing her \*517 proposed instructions

defining the standard of care which the law imposes upon an ophthalmologist. As a result, the plaintiff contends, in effect, that she was unable to argue her theory of the case to the jury that the standard of care for the specialty of ophthalmology was inadequate to protect the plaintiff from the incidence of glaucoma, and that the defendants, by reason of their special ability, knowledge and information, were negligent in failing to give the pressure test to the plaintiff at an earlier point in time which, if given, would have detected her condition and enabled the defendants to have averted the resulting substantial loss in her vision.

We find this to be a unique case. The testimony of the medical experts is undisputed concerning the standards of the profession for the specialty of ophthalmology. It is not a question in this case of the defendants having any greater special ability, knowledge and information than other ophthalmologists which would require the defendants to comply with a higher duty of care than that 'degree of care and skill which is expected of the average practitioner in the class to which he belongs, acting in the same or similar circumstances.' Pederson v. Dumouchel, 72 Wash.2d 73, 79, 431 P.2d 973 (1967). The issue is whether the defendants' compliance with the standard of the profession of ophthalmology, which does not require the giving of a routine pressure test to persons under 40 years of age, should insulate them from liability under the facts in this case where the plaintiff has lost a substantial amount of her vision due to the failure of the defendants to timely give the pressure test to the plaintiff.

The defendants argue that the standard of the profession, which does not require the giving of a routine pressure test to persons under the age of 40, is adequate to insulate the defendants from liability for negligence because the risk of glaucoma is so rare in this age group. The testimony of the defendant, Dr. Carey, however, is revealing as follows:

Q. Now, when was it, actually, the first time any complaint was made to you by her of any field or

83 Wash.2d 514, 519 P.2d 981, 67 A.L.R.3d 175

(Cite as: 83 Wash.2d 514, 519 P.2d 981)

visual field \*518 problem? A. Really, the first time that she really complained of a visual field problem was the August 30th date. (1968) Q. And how soon before the diagnosis was that? A. That was 30 days. We made it on October 1st. Q. And in your opinion, how long, as you \*\*983 nor have the whole history and analysis and the diagnosis, how long had she had this glaucoma? A. I would think she probably had it ten years or longer. Q. Now, Doctor, there's been some reference to the matter of taking pressure checks of persons over 40. What is the incidence of glaucoma, the statistics, with persons under 40? A. In the instance of glaucoma under the age of 40, is less than 100 to one per cent. The younger you get, the less the incidence. It is thought to be in the neighborhood of one in 25,000 people or less. Q. How about the incidence of glaucoma in people over 40? A. Incidence of glaucoma over 40 gets into the two to three per cent category, and hence, that's where there is this great big difference and that's why the standards around the world has been to check pressures from 40 on.

The incidence of glaucoma in one out of 25,000 persons under the age of 40 may appear quite minimal. However, that one person, the plaintiff in this instance, is entitled to the same protection, as afforded persons over 40, essential for timely detection of the evidence of glaucoma where it can be arrested to avoid the grave and devastating result of this disease. The test is a simple pressure test, relatively inexpensive. There is no judgment factor involved, and there is no doubt that by giving the test the evidence of glaucoma can be detected. The giving of the test is harmless if the physical condition of the eye permits. The testimony indicates that although the condition of the plaintiff's eyes might have at times prevented the defendants from administering the pressure test, there is an absence of evidence in the record that the test could not have been timely given.

Justice Holmes stated in Texas & Pac. Ry. v. Behymer, 189 U.S. 468, 470, 23 S.Ct. 622, 623, 47 L.Ed. 905 (1903):

What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard \*519 of reasonable prudence, whether it usually is complied with or not.

In The T. J. Hooper, 60 F.2d 737, on page 740 (2d Cir. 1932), Justice Hand stated:

(I)n most cases reasonable prudence is in fact common prudence; but strictly it is never its measure; a whole calling may have unduly lagged in the adoption of new and available devices. It never may set its own tests, however persuasive be its usages. Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission.

(Italics ours.)

Under the facts of this case reasonable prudence required the timely giving of the pressure test to this plaintiff. The precaution of giving this test to detect the incidence of glaucoma to patients under 40 years of age is so imperative that irrespective of its disregard by the standards of the opthalmology profession, it is the duty of the courts to say what is required to protect patients under 40 from the damaging results of glaucoma.

We therefore hold, as a matter of law, that the reasonable standard that should have been followed under the undisputed facts of this case was the timely giving of this simple, harmless pressure test to this plaintiff and that, in failing to do so, the defendants were negligent, which proximately resulted in the blindness sustained by the plaintiff for which the defendants are liable.

There are no disputed facts to submit to the jury on the issue of the defendants' liability. Hence, a discussion of the plaintiff's proposed instructions would be inconsequential in view of our disposition of the case.

The judgment of the trial court and the decision of the Court of Appeals is reversed, and the case is remanded for a new trial on the issue of damages

# Medical Practice Guidelines as Malpractice Safe Harbors: Illusion or Deceit?

Maxwell J. Mehlman

he idea that physicians should accept recommendations from learned colleagues on how to practice medicine is probably as old as medicine itself, but beginning around 1990, it took on new urgency in the face of rising health care costs, widespread, unjustifiable variation in practice patterns, concerns about medical errors and quality of care, and what some perceived to be perverse effects of the malpractice system. One solution put forward was practice guidelines, which the Institute of Medicine (IOM) defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."

## The Rise and Fall of Practice Guidelines as "Safe Harbors"

In 1991, Clark Havighurst and Mark Hall published law review articles recommending that practice guidelines be used to establish the standard of care in malpractice cases.<sup>2</sup> Hall preferred for guidelines to be irrebutable evidence of the standard of care, giving them "pre-emptive effect that precludes opposing testimony about the applicable standard of care."<sup>3</sup> Recognizing that guidelines might not be "definite" enough to serve this conclusory function, he suggested instead that state legislatures enact "variable immunity statutes" authorizing trial judges to determine if proffered guidelines were "authoritative and indisputably applicable." If guidelines met these criteria and defendant physicians showed that they had complied with the guidelines, then judges, without the need for further

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evidence, would be expected to issue directed verdicts in the defendants' favor.4 Moreover, Hall thought that guidelines should only have this conclusive effect if the defendant asserted compliance with a guideline as a defense, and not if the plaintiff sought to use the defendant's failure to comply with a guideline as evidence of malpractice. In other words, if a plaintiff produced evidence that a guideline was "authoritatively and indisputably applicable" and that the defendant had failed to adhere to it, then the defendant would be free to bring in opposing evidence, including expert witnesses, while the plaintiff would be precluded from offering similar evidence to dispute a defendant's claim that adherence to a guideline was an absolute defense. Hall rationalized this one-way-street approach by arguing that the "respectable minority" and "two schools of thought" doctrines showed that there often was more than one right way to practice medicine in a particular case:

With this possibility in mind, it makes eminent sense to hold that it is not conclusive for a plaintiff to establish that the defendant violated one established standard. However, the opposite holds for a defendant who complies with at least one established professional guideline: because it is not necessary for a doctor to show that unanimous professional consensus supports his conduct, a defense is sufficiently established if the doctor shows only that she complied with at least one respectable body of opinion.<sup>5</sup>

In 1990, the year before Havighurst's and Hall's articles were published, the Maine State Legislature adopted a proposal put forth by the Maine Medical Association to create guidelines for anesthesiology,

emergency medicine, obstetrics and gynecology, and later radiology, to adopt the guidelines as administrative rules of the state medical board, and to conduct a five-year-long demonstration project (subsequently renewed for another five years in 1997)6 in which physicians could assert compliance with the guidelines as a defense in a malpractice suit. The four specialties were chosen because of the frequency of malpractice suits against practitioners, the size of awards, the willingness of specialists in these areas to participate in the project (the cardiologists, for example, refused)<sup>7</sup>, and the existence of guidelines issued by their national organizations.8 The Maine legislation also made the use of guidelines one-way: "In any claim for professional negligence against a physician or the employer of a physician ... in which a violation of a standard of care is alleged, only the physician or the physician's employer may introduce into evidence, as an affirmative defense, the existence of the practice parameters and risk management protocols developed and adopted pursuant to [the law] for that medical specialty area."9

The Maine demonstration project appears to have enjoyed little success. Only once did a physician assert adherence to a guideline as a defense, and there is no clear indication that the project significantly lowered malpractice insurance premiums or health care costs. 10 Minnesota, Vermont, and Florida also enacted legislation in the early 1990s authorizing the creation of state-sanctioned practice guidelines and their use in malpractice cases. Like Maine, Minnesota provided for one-sided adherence to a guideline as an absolute defense to liability.11 In Vermont and Florida, guidelines apparently could be introduced by either side as evidence of whether the defendant acted in accordance with the standard of care.12 Neither Minnesota<sup>13</sup> nor Florida<sup>14</sup> appears to have issued any guidelines, however, and a 1993 report from the Office of Technology Assessment stated that "only three States [Maine, Minnesota, and Vermont] have attempted to formalize the role of guidelines in malpractice litigation and these efforts have yet to yield even anecdotal results."15 (Interestingly, in 1993 the Maryland legislature created a program to encourage the development of practice guidelines but, for reasons that are unclear, prohibited their use by any party as evidence in malpractice cases.<sup>16</sup>) At the federal level, Hall points out that the statute creating the Medicare Peer Review Organization (PRO) system contained a provision providing immunity from civil liability for anyone acting "in compliance with or reliance upon professionally developed norms of care and treatment applied by" a PRO, but notes that this protection has never been invoked because no suitable norms were ever

promulgated and because of confusing statutory language.<sup>17</sup> Congress in the early 1990s considered bills to promote the use of guidelines in litigation,<sup>18</sup> and the idea was endorsed by Bill Clinton when he was running for office and included as a pilot program in his 1993 health reform plan.<sup>19</sup> None of these efforts came to fruition, however.

#### Why Previous Attempts to Use Practice Guidelines As "Safe Harbors" Failed

What explains the failure of these attempts to allow practice guidelines to play a definitive role in malpractice litigation? One reason was the lack of enthusiasm by organized medicine. Concerned lest practice guidelines usher in an era of "cookbook medicine" in which physicians would lose their ability to make use of their experience and to exercise their clinical judgment, organized medicine was skeptical about guidelines in general and their use in malpractice litigation in particular. In 1989, for example, James Todd, then the president of the American Medical Association (AMA), emphasized that "you cannot restrict physicians to one procedure or series of procedures for a specific condition....No two patients are exactly alike and no two conditions are exactly alike. What we must do is provide physicians with parameters that give them the flexibility to utilize their own skills within an acceptable range of options."20 Arnold Rosoff cites a 1993 statement by AMA attorney Edward Hirshfeld that "the American Medical Association opposes, for the present at least, direct adoption of CPGs [clinical practice guidelines] as a legal standard and urges instead that they be used only as evidence of the customarily observed professional standard of practice and that their degree of authority be dependent upon the degree of their acceptance among medical practitioners."21 Rosoff notes that the AMA even was unwilling to support adherence to guidelines as an affirmative defense to malpractice liability.<sup>22</sup> Although Maine attempted to bar plaintiffs from using a failure to follow a guideline to inculpate a physician, moreover, doctors were no doubt concerned that other states would not impose such a limitation, which was borne out by the legislation in Vermont and Florida.

Another explanation for Maine's experience in particular was the impact of a previous 1987 change to the state's malpractice system which directed that malpractice claims be submitted to pretrial screening and mediation panels. As a result, a defendant wishing to assert an affirmative defense of adherence to a guideline would have to raise it at the pretrial screening stage, and it would be up to the panel to decide whether or not to accept the defense. The problem was that the screening legislation stipulated that, if

the panel unanimously rejected the defense because it concluded either that the guideline did not apply to the specific case or that the physician had failed to comply with the guideline, then that finding had to be made known to the jury. In other words, despite the intent of the legislature to restrict the benefit of guidelines to defendants, a screening panel's refusal to accept a guideline defense could be used offensively by the plaintiff as evidence of negligence. The only way to avoid this risk would be for the doctor to refrain from asserting the guideline as a defense,<sup>23</sup> and evidently most defendants decided to take this more cautious approach.

mative defense is not available. The plaintiff could provide such proof in one of two ways. First, the plaintiff could prove the case is not an Ob/Gyn case. A second argument would concede that the case is an Ob/Gyn case, but that the guidelines do not cover the particular treatment or scenario as presented in the plaintiff's cause of action.<sup>26</sup>

Arguably the most important reason why the guideline initiatives in the 1990s failed, however, was the shortcomings of the guidelines that were available at the time. Observing that hundreds of guidelines were being promulgated in response to the enthusi-

Arguably the most important reason why the guideline initiatives in the 1990s failed, was the shortcomings of the guidelines that were available at the time. Observing that hundreds of guidelines were being promulgated in response to the enthusiasm generated in medical and health-policy circles and that many of the guidelines made conflicting recommendations, the Office of Technology Assessment warned that "if courts and legislatures are not selective about which guidelines are introduced as evidence, these conflicts may find their way into the courts and further confuse rather than clarify the process of determining negligence."

Not only did the role of pretrial screening panels defeat the Maine legislature's desire that practice guidelines be used only as a shield by defendants, but the legislature failed to make the defense absolute. Hall acknowledged that adherence to a guideline "appears to provide only an additional piece of evidence for the jury to consider; nothing in the statute explicitly makes the parameters and protocols binding or conclusive."24 Commentators also noted that once the court admitted a guideline as a defense, "the plaintiff may present evidence on the issue of compliance and may attempt to use the parameters against the physician."25 In fact, the legal advisor to the Maine program argued that the rebuttability of the guideline defense was a major reason why the program's onesidedness would survive a constitutional challenge on the basis that it denied equal protection to plaintiffs:

The plaintiff can rebut the doctor's argument in court that the practice guidelines admitted are the applicable standard of care. For example, if a doctor relies on the Ob/Gyn guidelines and the plaintiff can prove those are not the appropriate standards for that particular case, then the affir-

asm generated in medical and health-policy circles and that many of the guidelines made conflicting recommendations, the Office of Technology Assessment (OTA) warned that "if courts and legislatures are not selective about which guidelines are introduced as evidence, these conflicts may find their way into the courts and further confuse rather than clarify the process of determining negligence."27 One suggestion was for courts to rely only on national guidelines, as Maine had attempted to do in selecting the specialty subjects for its program, but typically a number of national organizations were interested in a particular area of medicine, and these organizations often disagreed about what constituted proper care. Moreover, physicians and legislators were concerned that reliance on national standards could ignore local differences that could make the national standards overly burdensome and unrealistic. The OTA, predicting that this might cause state and local groups to modify national guidelines or to refuse to rely on them in programs such as Maine's, cautioned that

State guidelines initiatives such as these raise ... the potential for conflict between national, State,

and even institutional [e.g., hospital] guidelines. Most of Maine's guidelines were modeled closely from nationally recognized standards, but others were developed de novo by Maine physicians and could be construed as setting a precedent for reconversion to a more local standard of care. Developers of guidelines in Minnesota anticipate using national guidelines as models and amending them if necessary to conform to the realities of health care delivery in the State. In Vermont, the statutory description of guidelines could be interpreted as including even written institutional protocols.<sup>28</sup>

The IOM also was troubled by likely deference to parochial perspectives, warning that "local modifications of nationally produced guidelines will undermine one of the great benefits of these documents — standard approaches to clinical problem solving. In the meantime, however, the AMA has published a pamphlet to assist local organizations with guidelines modification processes."<sup>29</sup>

As described earlier, moreover, even if there were only one guideline covering a topic, physicians were concerned that slavish adherence to the guideline would deprive them of their critical ability to adjust care to suit individual patients. Consequently, as Hall observed, guidelines often included loopholes and escape clauses to cover specific cases:

The difficulty encountered to date is that what might otherwise be sufficiently precise guidelines are rendered entirely advisory or equivocal by waffling phrases and general disclaimers. For instance, the anesthesiology standards described previously call for monitoring blood pressure and heart rate 'at least every five minutes,' but, 'under extenuating circumstances, the responsible anesthesiologist may waive the requirement.' These two qualifications render the standard incapable of offering a definitive statement of whether every five minutes is often enough or too often.<sup>30</sup>

Built-in exceptions, which Hall blamed on what he called the "snowflake" theory that no two patients or conditions were exactly alike, clearly made it impossible for a guideline to serve as the standard of care: "It is impossible," he pointed out, "for physicians to have both wide clinical discretion and, at the same time, freedom from scrutiny in malpractice litigation."<sup>31</sup>

Another problem with the guidelines was that they could be biased by the interests of the organizations that issued them. Under the heading "The Specialists Windfall," for example, one MD/JD writing at the time cautioned that "physician specialists may realize economic gains when particular guidelines are promulgated. Currently, most guidelines are drafted by medical specialty organizations. To the extent that such guidelines purport to require the expertise of a specialist, the basis of such a requirement should be to assure high quality care, rather than to confer an economic advantage."<sup>32</sup> Other commentators pointed out that bias could be injected by differences in viewpoint as well as economic self-interest:

The value of the various outcomes may differ significantly depending on one's perspective, and such differences may explain differences in recommendations that have occurred. For example, an organization dedicated to reducing harm from cancer may place greater value on selected cancer screening interventions, even though such interventions might prove to be extremely costly for the magnitude of the benefit they provide. Another organization, whose purpose is to promote the overall health of society, may view the same evidence differently, preferring to concentrate on other proven interventions with greater impact on overall public health. Examples of this are the conflicting recommendations among current breast cancer and prostate cancer screening guidelines.33

The major weakness of practice guidelines in the 1990s, however, was the lack of scientific evidence supporting their recommendations. This stemmed partly from the failure of guideline issuers to consult the evidence that was available. One widely-cited study, for example, found that

less than 10% of the guidelines used and described formal methods of combining scientific evidence or expert opinion. Many used informal techniques such as narrative summaries prepared by clinical experts, a type of review shown to be of low mean scientific quality and reproducibility. Indeed, it was difficult to determine if some of the guidelines made any attempt to review evidence, as less than 20% specified how evidence was identified, and more than 25% did not even cite any references.<sup>34</sup>

The authors of this study evaluated 279 guidelines on a wide variety of topics according to 25 methodological standards and found that, in 1997, the guidelines on average satisfied no more than half of the standards. Furthermore, even if a guideline might have rested

initially on a sound scientific foundation, the science behind it very likely was no longer valid. A 2001 study of the 17 guidelines still in effect in 2000 out of the 19 guidelines that had been issued by the-then Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality) between 1990 and 1996 concluded that "more than three quarters need updating." 35

Given all the guideline deficiencies, in short, it comes as no surprise that guideline enthusiasts such as Hall were unable to obtain significant buy-in for their proposals. As the IOM stated in summarizing its overall observations about the state of the art of practice guidelines development,

most generally, the process of systematic development, implementation, and evaluation of practice guidelines based on rigorous clinical research and soundly generated professional consensus, although progressing, has deficiencies in method, scope, and substance. Conflicts in terminology and technique characterize the field; they are notable for the confusion they create and for what they reflect about differences in values, experiences, and interests among different parties. Public and private development activities are multiplying, but the means for coordinating these efforts to resolve inconsistencies, fill in gaps, track applications and results, and assess the soundness of particular guidelines are limited. Disproportionately more attention is paid to developing guidelines than to implementing or evaluating them. Moreover, efforts to develop guidelines are necessarily constrained by inadequacies in the quality and quantity of scientific evidence on the effectiveness of many services.36

Accordingly, the IOM concluded, guidelines were incapable of meeting the goals of their proponents:

Today the field of guidelines development is a confusing mix of high expectations, competing organizations, conflicting philosophies, and ill-defined or incompatible objectives. It suffers from imperfect and incomplete scientific knowledge as well as imperfect and uneven means of applying that knowledge. Despite the good intentions of many involved parties, the enterprise lacks clearly articulated goals, coherent structures, and credible mechanisms for evaluating, improving, and coordinating guidelines development to meet social needs for good-quality, affordable health care.<sup>37</sup>

As a result of these shortcomings, guidelines could neither rationalize nor reign in the excesses of medical practice, and they certainly could not fulfill the role envisioned for them in the malpractice system. Accordingly, when President Clinton in designing his health reform plan attempted to make good on his campaign pledge that "our doctors be given a set of national practice guidelines and if they follow these guidelines, it raises a presumption that they didn't do anything wrong," the White House Task Force on Health Care Reform ended up rejecting the idea, with the co-chair of the relevant working group observing that "there's not a lot of evidence out there. . . . It would be very difficult to recommend a federal policy regarding guidelines." <sup>38</sup>

## The Revival of Practice Guidelines on the Federal Political Scene

Despite this lackluster experience in the 1990s, the notion of using practice guidelines as a defense in malpractice cases recently has been revived. In the September 9, 2009, speech to a joint session of Congress in which he outlined his health reform initiative, President Obama stated that he had

talked to enough doctors to know that defensive medicine may be contributing to unnecessary costs. So I am proposing that we move forward on a range of ideas about how to put patient safety first and let doctors focus on practicing medicine. I know that the Bush Administration considered authorizing demonstration projects in individual states to test these issues. It's a good idea, and I am directing my Secretary of Health and Human Services to move forward on this initiative today.<sup>39</sup>

On June 11, 2010, the Agency for Healthcare Quality and Research (AHRQ) in the Department of Health and Human Services announced that it had awarded a number of demonstration and planning grants. The purpose of the grants, according to AHRQ, was to test models that, inter alia, "ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits; and...reduce liability premiums."40 One of the AHRQ planning grants, worth \$299,458, was given to Lynn Marie Crider of the Office for Oregon Health Policy and Research (OHPR) to "develop and implement a method for setting priorities for developing evidence-based practice guidelines, craft a broadly supported safe harbor legislative proposal that will define the legal standard of care, and develop a plan to evaluate the effectiveness of the legislative proposal, if enacted."<sup>41</sup> According to an OHPR job posting for a student researcher, the project will "explore a method for adopting evidence-based guidelines to address the clinical situations that result in significant numbers of patient injuries or medical liability claims."<sup>42</sup> The project will explore "linking the legal standard of care to compliance with the guidelines," the job description continues, in order to "provide physicians with greater clarity about the standard of care expected of them and assure them that, if they adhere to the guidelines, a 'safe harbor' will be provided in which the physician will not be found liable for harm resulting from failure to do something that is inconsistent with the guidelines," and in order to "reduce medical liability claims."<sup>43</sup>

It is conceivable that well-designed practice guidelines could improve the quality of patient care and reduce health care expenditures by discouraging docCould the new guidelines initiative actually achieve the ambitions of its supporters? Is there anything new to suggest that the current effort would be more successful than its predecessors in the early 1990s? Is the safe harbor concept sound scientifically? Can guidelines truly be "evidence-based"? Above all, would making guidelines safe harbors for defendants in malpractice cases be sound public policy?

## Would Using Practice Guidelines As Safe Harbors Be Scientifically Sound?

In order for defendants to avoid liability by showing that they adhered to a practice guideline, the guideline would have to accurately describe the proper standard of care for the case in question. This was problematic in the 1990s, and a survey of recent literature shows that it is still problematic now. For example, a panel of 26 experts from multiple disciplines (health, method-

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tors from ordering inappropriate services. Moreover, the current guideline initiative is supposedly based on an improved type of "evidence-based" guideline to be made possible by an expanded program of federally funded comparative effectiveness research, another element of President Obama's health agenda. The American Recovery and Reinvestment Act of 2009 (ARRA), for example, authorized the expenditure of \$1.1 billion to conduct research comparing "clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions."44 ARRA also established the Federal Coordinating Council for Comparative Effectiveness Research to foster optimum coordination of comparative effectiveness research conducted or supported by federal departments and agencies, while the 2010 health care reform legislation established the Center for Comparative Effectiveness Research within AHRQ and an independent Comparative Effectiveness Research Commission.45

ological, legal, bioethics, and lay persons) convened in 2008 to study practice guidelines found that "the lack of specificity of recommendations such as the common failure to give an age after which screening [for cancer and cardiovascular disease] is no longer recommended and the variability among guidelines limits their usefulness to physicians."46 The panel's explanations for these deficiencies echo criticisms similar to those that had been lodged against the earlier guideline efforts: "Although every organization presumably has access to the same body of evidence to develop guidelines, screening guidelines vary from aggressive to conservative. Insufficient available evidence may be responsible for some of the variability [but] biases on the part of authors and too great a reliance on expert opinion where evidence is lacking may also contribute."47 The IOM recently reached a similar conclusion after surveying the guideline landscape, finding "major gaps both in the identification and development of valid practice guidelines and in the actual use of practice guidelines by the physician community."48

Guidelines initiatives are still plagued by conflicting recommendations.<sup>49</sup> A 2009 article in the *Journal* of the American Medical Association (JAMA) gives a good example:

Although unanimity is the rule in individual guidelines, it can be strikingly absent when different guidelines are compared. The debate as to whether low-density lipoprotein cholesterol (LDL-C) or apolipoprotein B (apoB) is a more powerful marker of the risk of vascular disease illustrates that guideline groups may not just disagree — they actually may contradict each other. For instance, in the past 6 months, 4 reports have compared LDL-C and apoB, with 2 supporting LDL-C over apoB and 2 in favor of apoB for predicting cardiovascular risk. The 2 reports that favor LDL-C state categorically that there is no published evidence allowing apoB treatment targets to be established. The 2 that chose apoB cite multiple studies supporting their position in favor of an apoB target. Only one presents a complete, detailed, organized review and analysis of the evidence including the technical accuracy and reproducibility of the 2 measures.<sup>50</sup>

The example concludes with an especially revealing observation, about which more will be said later: "The discordance between the views on apoB vs LDL-C is disconcerting, but not surprising given the failure to even agree on what constitutes evidence or how that evidence should be graded." <sup>51</sup>

A major reason for the inconsistencies between guidelines continues to be bias on the part of guideline issuers.<sup>52</sup> Writing in the Archives of Internal Medicine in 2011, one group of authors points out that "improper bias in the CPG [clinical practice guideline] production process can have a potentially more widespread adverse effect on patient care than individual practitioners' COIs [conflicts of interest]."53 Bias stems partly from the lack of rules about the range of expertise and viewpoints that must be employed in the guideline-writing process: "Epidemiologists and economists are often minimally represented. Different topics require different repertoires of talents. Importantly, even when it is known that areas of legitimate controversy will be covered, there is often no attempt to ensure that all sides will have reasonable opportunity to present their evaluation of the evidence and participate in the decision-making process."54

In addition to professional biases, personal conflicts of interest corrupt the guideline issuance process.<sup>55</sup> "By favoring one test over another, or one therapy over another," the *JAMA* article cited above points

out, "guidelines often create commercial winners and losers, who cannot be disinterested in the result and who therefore must be separated from the process."56 Yet the guideline issuance process has failed to correct the problem. A study of the 17 cardiovascular guidelines issued most recently by the American College of Cardiology and the American Heart Association showed that 277 of the 498 (56%) individuals who participated in the PG [practice guideline] production process had a conflict of interest, most often as a consultant or advisory board member, followed by research grants, honoraria/speakers bureaus, and stock or other ownership.<sup>57</sup> The investigators found that chairs, co-chairs, and first authors of peer reviews had an even higher rate (81%).58 This was particularly troublesome, the investigators pointed out, "given the fact that many of the newest ACC/AHA guideline recommendations are based more on expert opinion than on clinical trial data."59 The study mentioned earlier in which guidelines were examined by a multidisciplinary panel similarly reported that

in the discussions, participants acknowledged that potential competing interests were not uncommon among sponsoring organizations and authors of CPGs. Avoidance of all potential CIs [conflicts of interest] in development of CPGs was emulated as ideal, but considered probably unrealistic, given the paucity of peerreviewed funding opportunities for development of evidence-informed CPGs and the scarcity of knowledgeable authors without CIs. An optimal approach for management of CIs in CPGs could not be agreed upon by participants. <sup>60</sup>

This observation points to a fundamental impediment to conflict-free guidelines: the lack of impartial funding for their creation. Even if commercial interests were barred from sponsoring the guideline process directly, Timothy Jost points out that they

play a major role in funding specialty societies and even patient disease organizations. Companies help sponsor specialty society annual meetings and journals and pay fees for space in exhibition halls at society meetings. Companies often offer their own marketing programs in tandem with specialty association meetings. Specialty societies play an active role in formulating practice guidelines, which can favor particular products or approaches to the treatment of diseases. Companies also fund patient disease organizations, which in turn pressure govern-

ment and insurers to cover particular products or procedures. <sup>61</sup>

Among the more notorious examples of conflicts of interest in the creation of guidelines is a guideline published in a leading cardiology journal by the Screening for Heart Attack Prevention and Education Task Force, composed of prominent cardiologists; it turned out that the publication of the guideline was paid for by a major drug company, the authors of the guideline failed to adequately disclose their financial relationships, and the guideline was never subjected to peer review.<sup>62</sup> Another prominent incident was the issuance of Lyme disease treatment guidelines by the Infectious Diseases Society of America (IDSA) disagreeing with the guidelines and practices of the International Lyme and Associated Diseases Society (ILADS), especially over whether there was such a condition as chronic Lyme disease that merited longterm antibiotic treatment.63 The controversy became bitter, with one article describing that

formal complaints have been filed and investigations launched against physicians treating Lyme disease on both sides of the debate. The two sides have battled in clinical trials, journals, press releases, letters, and testimony over state and federal legislation, court rooms, websites, and most recently, within the pages of their respective clinical practice guidelines. Less than a year after IDSA's revised guidelines were published, the *New England Journal of Medicine* arguably fanned the flames of dissent by publishing an article refuting the existence of 'chronic Lyme' disease. The article was written by many of IDSA's panelists. In response, ILADS issued a press release, questioning the journal's motives. <sup>64</sup>

The public dispute became so bitter that Connecticut Attorney General Richard Blumenthal opened an investigation in which he concluded that "the IDSA's 2006 Lyme disease guideline panel undercut its credibility by allowing individuals with financial interests — in drug companies, Lyme disease diagnostic tests, patents and consulting arrangements with insurance companies — to exclude divergent medical evidence and opinion."65 Only recently have steps been taken to remedy the conflict-of-interest problem, such as rules issued by the American College of Cardiology and the American Heart Association forbidding guideline committee members from having financial conflicts,66 and similar rules disseminated in April 2010 from the Centers for Medicare and Medicaid Services and the Council of Medical Specialty Societies.<sup>67</sup> Yet while the 2010 rules prohibit the pharmaceutical and medical device industries from paying for the development of guidelines, they do not forbid them from paying for "distribution, updating, and repurposing" of the guidelines. Furthermore, it is unclear whether there are enough experts without conflicts to produce scientifically well-informed guidelines. The cardiovascular guidelines study described earlier claimed to have found that there was still a sufficiently large pool of non-conflicted experts, but conceded that this finding "does not address the very important issue of the COIs of the professional societies that produce the guidelines, which often receive large donations from industry and rely on industry sponsorship and participation in scientific sessions."

One step that might lessen the problem of conflicts of interest would be if guidelines were peer-reviewed by disinterested experts before being finalized. But "few associations submit the final products of the guideline process for external review before they are accepted and, therefore, in a limited but real sense, the committee, which is a creation of the organization, becomes the final arbiter of its process." Furthermore, guidelines are often published in journals controlled by the specialty societies that issue them, and these journals "often must publish their guidelines essentially as is." <sup>72</sup>

Another flaw in the development process is that it tends to sanitize the resulting guidelines so that disagreements within the group that created it are papered over. As one article observes, "unanimity is not a natural component of science. Given the number and complexity of issues reviewed and given that scientific knowledge is at any moment incomplete, unanimity is obviously a tactic, not a necessary result. Debate may have been brisk within the committee but usually all evidence has been expunged from the final document."

A far greater deficiency in current guidelines, however, is the same major shortcoming that stymied the guidelines movement in the 1990s: the lack of scientific evidence backing up the recommendations. A 2009 analysis of guidelines issued by the American College of Cardiology and the American Heart Association found that, although "the significant increase in the quantity of scientific literature concerning cardiovascular disease published in recent years (along with the number of technical and medical advances) if aimed to address unresolved issues confronting guideline writers — should have resulted in guideline recommendations with more certainty and supporting evidence,"74 in fact "recommendations issued in current ACC/AHA clinical practice guidelines are largely developed from lower levels of evidence or expert opinion."75 Even worse, "the proportion of recommendations for which there is no conclusive evidence is also growing."<sup>76</sup> The authors of this study found it especially noteworthy that their findings "are reflective of a specialty — cardiology — that has a large pool of research to draw on for its care recommendations. Guidelines in other medical areas in which large clinical trials are performed less frequently may have an even weaker evidence-based foundation."<sup>77</sup> Another examination of cardiovascular guidelines in 2007

mentioned earlier, is that there is no consensus on what makes a guideline evidence-based. States one group of commentators:

While it is easy to say that one should follow only those guidelines that are 'evidence based,' very few guideline developers declare their documents to be non-evidence based, and there is ambiguity about what 'evidence based' really

Supporters of the current guideline initiative are optimistic that the new push for comparative effectiveness and other clinical research will enable guidelines to improve their evidentiary underpinnings. But these types of studies may not be the cure-all that is claimed. For example, the hope that good scientific evidence will eliminate the problem of bias and conflicts of interest is undermined by the fact that the investigators who conduct these studies are themselves plagued by conflicts. Even more striking is that there is no consensus on what makes a guideline evidence-based.

showed that "only 28% (range 21% to 41% between guidelines) of the 369 cardiovascular risk management recommendations in...nine prominent national evidence-based guidelines were directly supported by high-quality evidence."78 The same investigators also reviewed diabetes guidelines. "Given the widespread availability of electronic databases to search the literature," they stated, "one would expect that evidencebased guidelines would usually cite the same evidence. However, an analysis of 15 guidelines for type 2 diabetes mellitus revealed little overlap — only ten studies (less than 1% of all citations) were cited in at least six of these guidelines, and the most frequently cited study in these guidelines (the Diabetes Complication Control Trial, referenced in 11 of 15 guidelines) was conducted exclusively in patients without type 2 diabetes mellitus."<sup>79</sup> It is not surprising, therefore, that the IOM in 2009 declared that "even the most thoughtfully conceived and sophisticated practice guidelines have inadequacies in their evidence base...."80

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means in the context of guidelines. The term may be interpreted differently depending on who is referring to the guideline — the developer, who creates the guidelines, or the clinician, who uses them. To their developers, 'evidence-based guidelines' are defined as those that incorporate a systematic search for evidence, explicitly evaluate the quality of that evidence, and then espouse recommendations based on the best available evidence, even when that evidence is not high quality. However, to clinicians, 'evidence based' is frequently misinterpreted as meaning that the recommendations are based solely on high-quality evidence (i.e., randomized clinical trials [RCTs]).<sup>82</sup>

A 2008 critique in JAMA makes a similar point:

Underlying the logic of EBM [evidence-based medicine] is the vague definition of what qualifies as evidence-based standards. Who determines which practices to adopt and what standards to use; how are the relative risks, benefits, and costs considered, weighed, and reported? Organizations such as the Joint Commission, the National Quality Forum, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality have served as clearinghouses for the adoption of certain best practices. However, the methods are not fully

developed to determine when evidence is sufficiently strong, the feasibility in varying contexts is sufficiently robust, the costs or risks are small enough to encourage physician compliance, and recommendations are free of conflicts of interest. Overshadowed by these decisions is the fact that risks, benefits, and costs may vary for the patient, clinician, and payer.<sup>83</sup>

Even if everyone agreed on what should count as an evidentiary basis for guidelines, moreover, it is not clear that the clinical trials from which the evidence is supposed to be extracted are capable of providing the necessary knowledge. In one study, for example, the second most common reason that the investigators cited for downgrading recommendations in the supposedly evidence-based guidelines that they reviewed, a problem in 47% of their sample, "were concerns about the clinical relevance of the RCT [randomized controlled trial] - for example, the RCT reported the effect of the recommended therapy on surrogate outcomes only (e.g., levels of glucose, lowdensity lipoprotein cholesterol, or blood pressure) rather than patient-centered outcomes such as death, myocardial infarction, or stroke."84 The authors of the study emphasized that most common weakness in the guidelines, however, was the disconnect between the study population and the patient to whom the guideline ultimately will be applied: "The most frequent reason for downgrading RCT-based therapy recommendations (64 [51%] of the 126 cases) were concerns about the need to extrapolate from a highly selected RCT population to the scenario and/or the target population specified in the guideline." The investigators added that "the RCT was conducted to answer a particular question in a restricted study population but was then extrapolated in the guideline to justify using the tested intervention in a related, but different, clinical scenario and/or in a more general population."85

The illusion that broad guidelines can cover specific patients, one of the main objections that doctors have asserted against guidelines all along, continues to plague guidelines based on clinical trials not only because of the methodological limitations of such experiments but because of our growing awareness that patients respond significantly differently to treatments based on their individual genotypes, phenotypes, and the environmental conditions that affect them, which clinical trials do not often take into consideration. For this reason, physicians who understand the importance of personalized medicine remain skeptical of the new evidence-based initiative. The following interpretation for practitioners of how guidelines should be used is typical:

Rather than a strict set of steps, as in quality measures, the use of practice guidelines is analogous to consulting a cookbook to guide the creation of a dish. The recipes in a cookbook do not prevent a cook from tossing a handful of basil into a dish if the cook feels it would improve the flavor. Along the same concept, practice guidelines only suggest the best practice for treating a particular condition. Practice guidelines are not a stand-in for the knowledge that one gains from meaningful patient interaction. Only the treating physician knows the quirks and circumstances of a particular patient. Ultimately, the treatment decision must be a shared decision-making process between the physician and the patient by using the best scientific evidence from the literature.86

One of the salient differences between individual patients that clinical trials rarely take into account is patient preferences. An analysis in 1999 found that "few guidelines (21.5%)...discussed the role of patient preferences in choosing among the various health care options. Given the increasing appreciation of the importance of patient values in many clinical decisions, we believe this factor has not been adequately addressed in guidelines to date."87 There is nothing to indicate that the design of clinical trials has substantially changed in the interim. With clinical trials largely deaf to the fact that some patients are more willing to take greater risks for a potential benefit than other patients, guidelines based on the outcomes of the trials therefore will fail to reflect what should be a critical factor in clinical decision-making.

Finally, even if an evidence-based guideline was valid at one point in time, it may no longer be valid when a physician seeks to be guided by it or to employ adherence to it as a defense in a malpractice case. As Ronan Avraham observes,

Medical guidelines are especially vulnerable to becoming obsolete because these guidelines are currently created by organizations without the funding necessary to make continuous improvements as new research is released. Because the resources required to create comprehensive guidelines are expensive and time-consuming, the guidelines produced may already be obsolete by the time they are released or quickly thereafter.<sup>88</sup>

A good illustration of guideline obsolescence is a 2010 study of the effect of using different guidelines for percutaneous coronary intervention (PCI) as mea-

sures of appropriate practice for purposes of pay-forperformance initiatives.89 The PCI guidelines classify patients into one of four indication classes, which determines the appropriateness of giving them PCI. The authors explain that practice guidelines issued in 2001 were in force between 2003 and 2004, but it was not until the guidelines were revised in 2005 that they "most accurately capture the evidence available in 2003-2004 (and hence the most desirable approach to practice) [at that time]."90 As a result, "[if] care in 2003-2004 had been scored based on the evidence available at that time (reflected in the 2005 guidelines), over 40% of patients would have been judged to be in a different indication class than if that care had been scored based on the guideline available at the time (the 2001 guidelines)." In short, "directly translating CPGs into performance measures that purport to describe the quality and appropriateness of contemporary care can generate potentially misleading performance assessments."91

In view of these persistent problems, there may well be few guidelines, if any, that are authoritative enough to reflect proper clinical practice. The Obama Administration's stimulus money is funding some comparative effectiveness studies that might provide additional evidence on which to base guidelines, but this evidence is not yet available, and the methodological problems inherent in the evidence-gathering process make it far from certain that a substantial amount of suitable evidence will be produced for the foreseeable future. A more concerted effort also may be made someday to overcome the obstructive effects of bias and conflicts of interest, but it is not clear whether enough impartial experts can be found to avoid too great a loss of relevant medical and scientific expertise.

## Would Using Practice Guidelines As Safe Harbors Be Sound Policy?

The foregoing section raises serious doubts about whether practice guidelines will ever be designed well-enough to serve as the standard of care. Let us assume for the moment, however, that scientifically valid guidelines produced by disinterested parties do in fact exist. And let us ignore for the time being the lingering problem of how guidelines meant to apply to population groups rather than to individuals can accommodate patient preferences and medically relevant patient differences. In other words, let us assume that there is a properly produced guideline that tells us what the standard of care is in a particular patient's case. Clearly, a physician who complies with this guideline is entitled to use it persuasively in his defense.

But how would we identify such a guideline? How would we know, for example, that a guideline had been

properly produced and that it was based on sound scientific evidence? Moreover, how would we know that it was describing what constituted "reasonable" care, the care required by the applicable legal standard? An article describing practice guidelines in occupational and environmental medicine, for example, states that "the development of practice guidelines, if framed as recommendations for best practices in the prevention, diagnosis, treatment, and management of occupationally related health concerns and disability, can improve the quality of occupational medical practice and worker health and well-being."92 Would a guideline that described "best practices," a term often used interchangeably with "practice guidelines," be setting the legally appropriate reasonable standard of care, or a higher "optimal" standard? This may not be a problem if guidelines can only be offered defensively by defendants, since physicians would have to show that they had complied with the guideline's optimal recommendation in order to assert compliance as a defense, but that assumes that the evidentiary use of guidelines is restricted to the defendant, which, as discussed below, raises a host of practical, equitable, and constitutional objections. In any event, even if guidelines could only be used defensively, how would we know if, instead of representing a reasonable or optimal standard of care, the guideline described substandard care? What prevents a guideline being issued by a physician group intent on setting the bar so low that its members effectively obtained immunity from liability?

How are these issues addressed under the current system? At present, the task of ensuring that guidelines are valid descriptors of behavior that meets the applicable legal standard is a joint enterprise, involving both the judicial system and the medical system. The medical system supplies the guidelines and the factual and scientific expertise to enable their assessment by the judicial system. Contrary to complaints from critics of the jury system such as Philip K. Howard,93 moreover, it is primarily judges rather than juries who perform the validation function in the judicial system, since while juries often must determine how the defendant acted and how much weight to give the evidence of how the defendant should have acted, it is the judge who decides if the evidence is admissible and if it is conclusive enough that a jury trial to decide whether the defendant met the standard of care can be avoided.

How well is this joint enterprise performing its task? The only published study to date of cases in which the parties sought to utilize practice guidelines, an analysis by Hyams, Shapiro, and Brennan in 1996, found 28 cases in which guidelines were "used successfully"

between 1980 and 1994,94 and cited no cases in which guidelines had been used improperly. My research assistant Kelsey Marand and I updated this study by examining cases reported between 1995 and 2011. We found a total of 24 additional reported cases. Guidelines were used successfully as a defense by defendants in 9 of the cases and by plaintiffs as inculpatory evidence in 11. In 4 cases, the courts determined that guidelines offered by plaintiffs were not inculpatory. In 4 cases, guidelines were relied upon by both parties. In all of the cases in which guidelines were successfully asserted as inculpatory, the guidelines were deemed "some evidence." In 6 of the cases in which guidelines were successfully used defensively, adherence to the guideline constituted some evidence; in 2, it gave rise to a rebuttable presumption. In their 1996 study, Hyams and his colleagues also surveyed malpractice lawyers, half of whom stated that they were aware of guidelines and a substantial number of whom stated that they gave heed to guidelines in deciding whether or not to take a case and in settlement negotiations,95 and there is no reason to believe that guidelines have stopped playing this pre-trial role, or that they now do so less efficiently. Based on the available data, it is perhaps difficult to be certain that the current legal/medical approach to practice guidelines in malpractice cases is running flawlessly, but the important thing is that there is no evidence that it is not running well.

Fair enough, supporters of safe harbors may say, but wouldn't their approach, in which the role of the courts in determining whether guidelines establish the standard of care would be reduced or eliminated in favor of the medical system, perform even better? The available evidence, described in this article, overwhelmingly indicates that it would not. Imagine, for example, that a medical group has issued a practice guideline and that a physician wishes to assert compliance with the guideline as a defense. If a judge did not determine if the guideline established the proper standard of care, who would? Would the fact that a medical group had issued the guideline be sufficient? What if the group in question, for example, was the Association of American Physicians and Surgeons, whose executive director states that "Comparative Effectiveness Research (CER) won't buy anything for you; it will just pay bureaucrats and researchers"96 and whose newsletter describes evidence-based medicine as "a greater merger of state and corporate power: Mussolini's definition of fascism"?97

Some commentators have suggested that authoritativeness can be achieved if the government issues, 98 or at least certifies, 99 practice guidelines. But others object to government-issued guidelines as anti-pluralist, 100 anticompetitive, 101 and an invitation to gov-

ernment rationing of health care. 102 Critics of government guidelines also point to incidents like the recent controversy over recommendations for mammograms issued by the U.S. Preventive Services Task Force as demonstrating the high and potentially unsustainable political costs of government-issued guidelines. 103

As for guidelines issued by insurance companies and other private third-party payers, only Hall seriously suggests that courts accept them, arguing that judges should respect the fact that "a sizeable number of patients and physicians agree to be bound by the standard by choosing to enroll with or work under the particular insurance plan."104 But Hall is ignoring the fact that few patients or physicians these days have much choice about which plans to associate with, and other scholars reject the use of guidelines issued by private insurers to establish the standard of care because, as one article explains, insurance-sourced guidelines "are meant to apply only to their beneficiaries and may recommend limiting care based on cost concerns."105 Avraham goes one step further than Hall in relying on market mechanisms by suggesting that private, for-profit companies should create and sell guidelines; to assure the quality of the guidelines, patients would be able to obtain damages from guideline-makers in the event that their recommendations proved to be substandard. 106 Where the money to pay for the guidelines is to come from and why allowing patients injured by malpractice to sue guideline issuers is better than allowing them to sue the physicians directly is not made clear.

Another alternative might be to entrust guideline development to some respected, independent source of medical expertise, <sup>107</sup> such as the IOM. Yet it is hard to imagine how even the distinguished members of the IOM could rationalize the more than 2,000 guidelines on file so far at the AHRQ's National Guidelines Clearinghouse, reconcile competing medical viewpoints, avoid bias and conflicts without losing the necessary expertise, keep up with changing science, and avoid slowing innovation by being too parochial or by not updating their recommendations often enough to accommodate medical advances.

Given the difficulties of identifying a single, authoritative guideline source, the only remaining option would seem to be to allow defendants to find a safe harbor in *any* practice guideline, which was actually one of the alternatives Mark Hall originally suggested. <sup>108</sup> But without some way to ensure that the guideline met acceptable standards, this would spur a race to the bottom in which fringe medical groups issued minimalist recommendations that improperly immunized its members from suit and in which the quality of patient care ultimately suffered. <sup>109</sup>

Finally, the safe harbors approach implies that no one can challenge the validity of a guideline in court, not only the plaintiff, but also not any other medical experts. Such a gag rule would be a radical departure from current law, but also from the scientific process itself, which the IOM itself embodies in its commitment to facilitating "discussion, discovery, and critical, cross-disciplinary thinking." In the scientific process, questioning accepted wisdom is vital to ensure scientific accuracy and progress.

In short, it is inescapable that the legal system would have to continue to play a major role under a safe harbors regime. Judges would have to decide the admissibility and conclusiveness of guidelines. If the guideline were determined to be authoritative, accurate, applicable, and conclusive, the judge would withhold the standard-of-care issue from the jury; where adherence to the guideline was offered as a defense, the result would be a judgment for the defendant. Moreover, judges and juries would have to decide whether or not the defendant had actually followed the guideline, and if plaintiffs were permitted to assert a failure to comply as evidence of negligence and did so successfully, juries also might have to calculate damages. As the earlier discussion shows, a robust role for the legal system was contemplated for the Maine guideline program; the only previous attempt to establish guidelines as the standard of care recognized it could not take cases completely away from judges and juries.

So, if judges and juries must continue to play their traditional roles, what would be different under a safe harbors approach? Would the use of guideline evidence be restricted to one side, so that the plaintiff could not introduce the failure to comply as evidence of wrongdoing? Would only the defendant be able to offer evidence about the authoritativeness of a guideline, about whether it applied in the case in question, or about whether the defendant in fact followed the guideline? Would the plaintiffs be allowed to argue against the guideline, but not to bring in expert witnesses in support of their arguments?

Although a full discussion of constitutionality is beyond the scope of this article, such distorted rules might well be found to deny patients injured by malpractice due process and equal protection. But in addition, there is nothing that would justify such unfairness. The rationales offered in support of the attempted one-sidedness of the Maine program — reducing defensive medicine and non-meritorious lawsuits, avoiding a battle of the experts, and encouraging sufficient physician buy-in — are either superfluous or rest on partisan misrepresentations of the malpractice system. The existence and extent of true defensive medicine is highly exaggerated, and evidence shows

that what doctors supposedly do to avoid liability provides net health benefits to their patients. Juries have been shown to be quite capable of understanding and evaluating expert testimony. As Nance and I explain in our Health Courts monograph, truly frivolous suits are at most infrequent, and the system actually does a decent job of weeding out invalid claims. 112 And if medicine begins to produce high-quality, unbiased, evidence-based guidelines that reflect the correct standard of care, the case law demonstrates that physicians who adhere to the guidelines in the proper circumstances typically gain substantial protection from liability, which along with other health reform initiatives such as pay-for-performance<sup>113</sup> should ensure substantial acceptance of high-quality guidelines by physicians.

In short, the safe harbors concept rests either on an illusion or on a deception. Either its proponents incorrectly believe that many practice guidelines exist that are capable of serving a safe harbors function or that they easily can be created and also erroneously believe that the judicial system can be substantially circumvented and still produce just results, or they know these not to be true but hope that distortions of the malpractice system and unrealistic expectations for guidelines can induce politicians to eviscerate, at patients' expense, the functions historically reserved for the law.

This leads to one final point: no other profession has gained the leverage that physicians are seeking from a safe harbors regime. Most other professions have promulgated the equivalent of practice guidelines, but in no case are their guidelines accorded automatic admissibility and conclusive legal effect, let alone one-sided application.114 The rules governing the conduct of lawyers, in fact, contain explicit disclaimers against even giving them a presumptive effect.<sup>115</sup> As for one-sidedness, Michelle Mello correctly observes that "there are exceptions to the rule of symmetry, but they are few and far between, and each is justified by an important policy concern."116 A departure from this long-standing status quo, and especially the unfairness that a one-sided approach would impose on patients injured by malpractice, would require extraordinary justification. As this article shows, no such grounds exist.

#### Conclusion

Medical practice guidelines have an important role to play as potential evidence of the standard of care. There is no convincing reason, however, why they should be treated any differently than other forms of expert evidence, or than all other professional standards. Judges must decide threshold questions of guideline admissibility using evidence offered by medical experts subject to cross-examination so that valid guidelines can

be identified. The judicial system also must determine whether evidence from admissible guidelines is conclusive, and whether or not defendants followed the guidelines. If the judge does not regard an admissible practice guideline as conclusive on the issue of the standard of care, then the fact-finder must be allowed to consider it along with other evidence introduced by both sides. Unquestionably, guidelines must be able to be introduced offensively as well as defensively. Only if the law continues to perform its time-tested functions in this way can the proper balance of power between the medical profession and the public interest be maintained.

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#### References

- Institute of Medicine, National Academies of Science, Clinical Practice Guidelines: Directions for a New Program, M. J. Field and K. N. Lohr, eds. (Washington, D.C.: National Academies Press, 1990): at 38 (hereinafter cited as 1990 IOM Report).
- C. C. Havighurst, "Practice Guidelines for Medical Care: Policy Rationale," St. Louis University Law Journal 34 (Summer 1990): 777-819, at 783; M. A. Hall, "The Defensive Effect of Medical Practice Policies in Malpractice Litigation," Law and Contemporary Problems 54, nos. 1-2 (1991): 119-145, at 130.
- 3. *Id.* (Hall), at 131.
- 4. Id., at 135.
- 5. Id., at 131.
- J. Begel, "Maine Physician Practice Guidelines: Implications for Medical Malpractice Litigation," Maine Law Review 47, Winter (1995): 69-103, at 86.
- 7. Id., at 342.
- 8. W. R. Trail and B. A. Allen, "Government Created Medical Practice Guidelines: The Opening of Pandora's Box," Journal of Law & Health 10, no. 2 (1995/1996): 231-258, at 245.
- 9. Me. Rev. Stat. Ann. tit. 24, 2975(1) (West Supp. 1993-1994).
- A. J. Rosoff, "Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines," *Journal of Health Politics, Policy, and Law* 26, no. 2 (2001): 327-368, at 343.
- 11. Id., at 340.
- See Trail and Allen, supra note 8, at 244; A. L. Hyams, D. W. Shapiro, and T. A. Brennan, "Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective," Journal of Health Politics, Policy, and Law 21, no. 2 (1996): 289-313, at 307-308.
- 13. See Trail and Allen, supra note 8, at 247.
- 14. See Hyams, Shapiro, and Brennan, supra note 12, at 308.
- Office of Technology Assessment, Impact of Legal Reforms on Medical Malpractice Costs, 1993, available at <a href="http://www.fas.org/ota/reports/9329.pdf">http://www.fas.org/ota/reports/9329.pdf</a>> (last visited April 4, 2012).
- See Rosoff, supra note 10, at 335; Trail and Allen, supra note 8, at 248.
- 17. See Hall, *supra* note 2, at 137-138.
- Id.; Hyams, Shapiro, and Brennan, supra note 12, at 308-310;
   J. D. Ayres, "The Use and Abuse of Medical Practice Guidelines," Journal of Legal Medicine 15, no. 3 (1994): 421-443, at 422.
- See Hyams, Shapiro, and Brennan, supra note 12, at 308-310;
   Rosoff, supra note 10, at 340.

- J. S. Todd, "Only Parameters Will Give MDs Needed Flexibility," American Medical News, January 6, 1989, at 15.
- 21. See Rosoff, supra note 10, at 343.
- 22. See Begel, *supra* note 6, at 342.
- 23. *Id.*, at 86; see Hyams, Shapiro, and Brennan, *supra* note 12, at 306-307; Rosoff, *supra* note 10, at 343.
- 24. See Hall, supra note 2, at 135.
- 25. G. W. Kuc, "Comment: Practice Parameters as a Shield Against Physician Liability," *Journal of Contemporary Health Law & Policy* 10, Spring (1994): 439-468, at 441.
- 26. See Trail and Allen, supra note 8, at 245.
- 27. See Office of Technology Assessment, supra note 15, at 33.
- 28 Id
- 29. See Ayres, supra note 18, at 429.
- 30. See Hall, supra note 2, at 143.
- 31. Id.
- 32. Id., at 436.
- 33. T. M. Shaneyfelt, M. F. Mayo-Smith, and J. Rothwang, "Are Guidelines Following Guidelines? The Methodological Quality of Clinical Practice Guidelines in the Peer-Reviewed Medical Literature," JAMA 281, no. 20 (1999): 1900-1905, at 1904.
- 34. Id., at 1903-1904.
- 35. P. G. Shekelle, E. Ortiz, S. Rhodes, S. C. Morton, M. P. Eccles, J. M. Grimshaw, and S. H. Woolf, "Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines: How Quickly Do Guidelines Become Outdated?" JAMA 286, no. 12 (2001): 1461-1467, at 1466.
- 36. See 1990 IOM Report, supra note 1, at 6.
- 37. Id., at 15.
- 38. See Hyams, Shapiro, and Brennan, supra note 12, at 309.
- 39. Obama's Health Care Speech to Congress, September 9, 2009, available at <a href="http://www.nytimes.com/2009/09/10/us/politics/10obama.text.html?pagewanted=1&%2360;!">http://www.nytimes.com/2009/09/10/us/politics/10obama.text.html?pagewanted=1&%2360;!</a>
   Undefined%20dynamic%20function%20data\_sanitationlib::sanitize\_string:1%20called &%2362;> (last visited April 4, 2012).
- Agency for Healthcare Quality and Research, HHS Announces Patient Safety and Medical Liability Demonstration Projects, Press Release, June 11, 2010.
- 41. Id.
- 42. Oregon Masters of Public Health, Field Experience and Internships Opportunities, available at <a href="http://www.oregonmph.org/content/field-experience-internship-opportunities">http://www.oregonmph.org/content/field-experience-internship-opportunities</a> (last visited April 4, 2012).
- 43. Id.
- 44. M. C. Weinstein and J. A. Skinner, "Comparative Effectiveness and Health Care Spending: Implications for Reform," New England Journal of Medicine 362, no. 5 (2010): 460-465.
- H. R. 3590. Patient Protection and Affordable Care Act, 111th Cong., 2nd sess. (2010).
- 46. A. M. Sawka, L. Magalhães, A. Gafni, and G. F. Lewis, "Competing Interests in Development of Clinical Practice Guidelines for Diabetes Management: Report from a Multidisciplinary Workshop," *Journal of Multidisciplinary Healthcare* 2008, no. 1 (2008): 29-34.
- 47. Id.
- 48. R. F. Hall, "Right Question, Wrong Answer: A Response to Professor Epstein and the 'Permititis' Challenge," *Minnesota Law Review Headnotes* 94 (Spring 2010): 50-84, at 75.
- 49. S. Keyhani, A. Kim, M. Mann, and D. Korenstein, "A New Independent Authority Is Needed to Issue National Health Care Guidelines," *Health Affairs* 30, no. 2 (2011): 256-265, at 259-260; A. D. Sniderman and C. D. Furberg, "Why Guideline-Making Requires Reform," *JAMA* 301, no. 4 (2009): 429-431.
- 50. See Sniderman and Furberg, supra note 49, at 430.
- 51. Id. (emphasis added).
- 52. T. B. Mendelson, M. Meltzer, E. G. Campbell, A. L. Caplan, and J. N. Kirkpatrick, "Conflicts of Interest in Cardiovascular Clinical Practice Guidelines," *Archives of Internal Medicine* 171, no. 6 (2011): 577-584; see Keyhani et al., *supra* note 48; Sniderman and Furberg, *supra* note 49.
- 53. See Mendelson et al., supra note 52, at 577.

- 54. See Sniderman and Furberg, supra note 49, at 429.
- 55. T. Stolzfus Jost, "Oversight of Marketing Relationships between Physicians and the Drug and Device Industry: A Comparative Study," American Journal of Law & Medicine 36, nos. 2-3 (2010): 326-342, at 327.
- 56. See Sniderman and Furberg, supra note 49, at 430.
- 57. See Mendelson et al., supra note 52, at 578.
- 58. Id.
- 59. Id., at 579.
- 60. See Sawka et al., supra note 46, at 33.
- 61. See Jost, *supra* note 55, at 332-333.
- 62. See Mendelson et al., supra note 52, at 578-579.
- 63. S. Ronn, "In the Lymelight: Law and Clinical Practice Guidelines," *Southern Medical Journal* 102, no. 6 (2009): 626-630, at 627.
- 64. Id., at 627.
- 65. *Id.*, at 628. See also R. Blumenthal, "Conn. Att'y Gen'l: Conflicts of Interest in Treatment Guidelines," *The Day*, July 19, 2009, *available at* <a href="http://www.theday.com/apps/pbcs.dll/article?AID=/20090719/OP05/307199960&template">http://www.theday.com/apps/pbcs.dll/article?AID=/20090719/OP05/307199960&template</a> (last visited April 4, 2012).
- 66. See Mendelson et al., supra note 52, at 580.
- 67. Council of Medical Specialty Societies, Code for Interactions with Companies, available at <a href="http://www.cmss.org/upload-edFiles/Site/CMSS\_Policies/CMSS%20Code%20for%20">htteractions%20with%20Companies%204-19-10.pdf</a> (last visited April 4, 2012); R. Avraham, "Clinical Practice Guidelines: The Warped Incentives in the U.S. Healthcare System," American Journal of Law & Medicine 37, no. 1 (2011): 7-40, at 20
- 68. See Avraham, supra note 67, at 29.
- 69. See Mendelson et al., supra note 52, citing D. Van Wyck, K. U. Eckardt, K. Uhlig, M. Rocco, and A. Levin, "Response to 'Influence of Industry on Renal Guideline Development," Clinical Journal of the American Society of Nephrology 2, no. 1 (2007): 13-14.
- 70. Id., at 581.
- 71. See Sniderman and Furberg, supra note 49, at 429.
- 72. *Id.*, at 430-431.
- 73. Id., at 430.
- P. Tricoci, J. M. Allen, J. M. Kramer, R. M. Califf, and S. C. Smith, Jr., "Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines," *JAMA* 301, no. 8 (2009): 831-841, at 832.
- 75. Id., at 832.
- 76. Id., at 831.
- 77. Id., at 835.
- 78. F. A. McAlister, S. van Diepen, R. S. Padwal, J. A. Johnson, and S. R. Majumdar, "How Evidence-Based Are the Recommendations in Evidence-Based Guidelines?" *PLoS Medicine* 4, no. 8 (2007): e250 at e250.
- 79. *Id*.
- 80. IOM, Initial National Priorities for Comparative Effectiveness Research (Washington, D.C.: National Academies Press, 2009): at 30.
- 81. See Sawka et al., supra note 46, at 33.
- 82. See McAlister et al., supra note 78, at e250.
- 83. S. C. Mathews and P. J. Provonost, "Physician Autonomy and Informed Decision Making: Finding the Right Balance for Patient Safety and Quality," *JAMA* 300, no. 24 (2008): 2913-2915, at 2915.
- 84. *Id*.
- 85. See McAlister et al., *supra* note 78, at e250.
- 86. K. C. Chung and M. J. Shauver, "Crafting Practice Guidelines in the World of Evidence-Based Medicine," *Plastic and Reconstructive Surgery* 124, no. 4 (2009): 1349-1354, at 1350.
- 87. See Shaneyfelt et al., supra note 33, at 1904. See also L. H. Harpole, M. J. Kelley, G. Schreiber, E. M. Toloza, J. Kolimaga, and D. C. McCrory, "Assessment of the Scope and Quality of Clinical Practice Guidelines in Lung Cancer," Chest 123, Supp.

- (2003): 7S-20S, at 17S and P. S. Hinds, J. S. Gattuso, E. Barnwell, M. Cofer, L. Kellum, S. Mattox, G. Norman, B. Powell, E. Randall, and C. Sanders, "Translating Psychosocial Research Findings into Practice Guidelines," *JONA* 33, nos. 7-8 (2003): 397-403 at 397-398.
- 88. See Avraham, supra note 67, at 29.
- 89. G. A. Lin, R. F. Redberg, H. V. Anderson, R. E. Shaw, S. Milford-Beland, E. D. Peterson, S. V. Rao, R. M. Werner, and R. A. Dudley, "Impact of Changes in Clinical Practice Guidelines on Assessment of Quality of Care," *Medical Care* 48, no. 8 (2010): 733-738.
- 90. Id., at 734.
- 91. Id.
- 92. J. Harris, "Development, Use, and Evaluation of Clinical Practice Guidelines," Journal Occupational & Environmental Medicine 39, no. 1 (1997): 23-34 (emphasis added); see also Chung and Shauver, supra note 86; R. N. Murphy, "Legal and Practical Impact of Clinical Practice Guidelines on Nursing and Medical Practice," Nurse Practitioner 22, no. 3 (1997): 138-148.
- 93. P. K. Howard, Making Civil Justice Sane, City Journal, April 17, 2006, available at <a href="http://www.city-journal.org/html/16\_2\_civil\_justice.html">http://www.city-journal.org/html/16\_2\_civil\_justice.html</a> (last visited November 12, 2006).
- 94. See Hyams et al., supra note 12, at 295.
- 95. Id., at 292.
- 96. J. M. Orient, "What Healthcare Reform 'Comparative Effectiveness Research' Means to You," Association of American Physicians and Surgeons, December 13, 2010, available at <a href="http://www.aapsonline.org/index.php/article/what\_healthcare\_reform\_comparative\_effectiveness\_research\_means\_to\_you/">http://www.aapsonline.org/index.php/article/what\_healthcare\_reform\_comparative\_effectiveness\_research\_means\_to\_you/</a>> (last visited April 4, 2012).
- 97. Association of American Physicians and Surgeons, "The Standard of Care," *AAPS Newsletter* 62, no. 1 (January 2006), *available at* <a href="http://www.aapsonline.org/newsletters/jan06.php">http://www.aapsonline.org/newsletters/jan06.php</a> (last visited April 4, 2012).
- 98. A. Tzeel, "Clinical Practice Guidelines and Medical Malpractice," *Physician Executive* 36 (March-April 2002): 36-39 at 38.
- 99. See Rosoff, supra note 10, at 357.
- 100. See Rosoff, *supra* note 10, at 327.
- 101. *Id.*; Avraham, *supra* note 67.
- 102. See Rosoff, supra note 10, at 328.
- 103. See Keyhani et al., supra note 49, at 262.
- 104. See Hall, supra note 2, at 140.
- 105. See Keyhani et al., supra note 49, at 257.
- 106. See Avraham, *supra* note 67, at 31.
- 107. See Rosoff, *supra* note 10, at 328.
- 108. See Hall, supra note 2, at 131.
- 109. See Havighurst, supra note 2, at 789.
- Institute of Medicine, "About the IOM," available at <a href="http://www.iom.edu/About-IOM.aspx">http://www.iom.edu/About-IOM.aspx</a>> (last visited April 4, 2012).
- 111. See Rosoff, *supra* note 10, at 344; Begel, *supra* note 6, at 93-97. But see M. M. Mello, A. Chandra, A. A. Gawande, and D. M. Studdert, "National Costs of the Medical Liability System," *Health Affairs* 29, no. 9 (2010): 1569-1577.
- 112. M. J. Mehlman and D. A. Nance, *Medical Injustice: The Case Against Health Courts* (Washington, D.C.: American Association for Justice, 2007): at 7.
- 113. See Lin et al., *supra* note 89, at 735-736.
- 114. See Mello, *supra* note 111, at 660-661, 695, 701.
- 115. ABA Model Code of Professional Responsibility, Preliminary Statement, 1983, available at <a href="http://www.law.cornell.edu/ethics/aba/mcpr/MCPR.HTM">http://www.law.cornell.edu/ethics/aba/mcpr/MCPR.HTM</a> (last visited April 4, 2012); ABA Model Rules for Professional Conduct, Preamble and Scope, at [14], available at <a href="http://www.americanbar.org/groups/professional\_responsibility/publications/model\_rules\_of\_professional\_conduct/model\_rules\_of\_professional\_conduct\_preamble\_scope.html">http://www.americanbar.org/groups/professional\_responsibility/publications/model\_rules\_of\_professional\_conduct\_preamble\_scope.html</a> (last visited April 4, 2012).
- 116. See Mello, *supra* note 111, at 695.