

Expertise in Law, Medicine, and Health Care

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Abstract As the practice of science-based medical evidence has challenged the medical profession to consider the scientific bases for its methods and procedures, on a seemingly parallel path, the United States Supreme Court's 1993 decision in *Daubert v. Merrell Dow Pharmaceuticals* has challenged the legal system to consider the science underlying claims of medical expertise. This article examines how the legal system has responded to that challenge and why the response has been more limited than many had expected; the implications of the legal system's approach to scrutiny of claims of medical expertise for the practice of science-based medical evidence; and, the central elements of any meaningful change in legal assessments of expertise in medicine and health care.

Physicians offer expert testimony in a wide variety of civil and criminal proceedings that may directly involve the provision of health care (e.g., the standard of care in medical malpractice claims), that may indirectly involve the provision of health care (e.g., the prognosis of a claimant injured in an automobile accident), or that may not at all involve the provision of health care (e.g., the cause of death in a homicide prosecution or toxic tort claim). Even if a physician's provision of expert testimony

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is so closely tied to the provision of health care as to constitute the practice of medicine (Simon and Shuman 1999), no formal mechanism exists within the health care professions to approve the qualifications of purported experts or the reliability of their methods and procedures beyond the generic license to practice. Thus it falls to the courts to fashion mechanisms to address these purported experts' qualifications and their methodologies. This article addresses the mechanisms that courts have fashioned and the results they generate for science-based medical evidence. Whether the law regards as expert what a majority of the medical profession or particular groups of physicians may regard as expert can have a profound affect on the outcome of legal proceedings as well as the practice of medicine. As the practice of science-based medical evidence has grown, emphasizing "a structured critical examination of medical research literature, and a relative deemphasis of anecdote and personal heuristics" (Cynthia D. Mulrow and Kathleen N. Lohr in this special issue), its potential impact on the law and the law's potential impact on the practice of science-based medical evidence will be shaped in no small way by how the law assesses expertise in medicine and health care.

To understand how the law addresses claims of expertise in medicine and health care requires an understanding of two very different *ideals* about trials that vie for dominance in the U.S. judicial system. These two ideals, represented by the traditional adversarial approach and the gatekeeper approach, reflect two different ways of accommodating the tension among core values at stake in the dispute resolution process—accuracy, fairness, efficiency, consistency, and accessibility. The strength of the support for these differing accommodations has vacillated over time and frequently has varied within a jurisdiction according to the evidence at issue or the context in which admission is sought. For example, while the traditional adversary approach retains its hold in criminal cases and most categories of civil cases including medical malpractice cases in most jurisdictions, the gatekeeper approach has recently made substantial inroads in toxic tort and products liability cases in many of those jurisdictions. Accurate prediction of how courts will respond to a particular claim of expertise in medicine or health care, or a meaningful attempt to change that approach, requires an understanding of the ideals represented by the traditional adversary and gatekeeper approach and their effect on the admission of evidence.

Thus this article begins by exploring these models and their implications for the admissibility of science-based medical evidence. Of the two, the language of the gatekeeper model, invoking falsifiability, error rates,

and peer review, appears most compatible with the concept of science-based medical evidence. Accordingly, the article then examines the impact of the cases that have ushered in the gatekeeper model on the admissibility of claims of medical expertise in both civil and criminal litigation. Concluding that the formal adoption of the gatekeeper model has had only a limited effect on the admissibility of claims of medical expertise—largely in raising the threshold for plaintiffs in products liability and toxic tort claims, the article then addresses the temporal, tactical, and philosophical barriers to a more informed application of science-based medical evidence in law. Finally, the article suggests several strategies for a more informed judicial response to claims of expertise in medicine and health care, including more rigorous scrutiny of expert testimony across the judicial spectrum, greater attention to the substantive legal standards that drive the need for expert testimony, and increased efforts to address the scientific education of lawyers.

The Traditional Adversarial System Approach

Although critics often use the word “adversarial” pejoratively, the American legal system rejects the civil law’s inquisitorial model and embraces the adversarial model as a novel vehicle to achieve a panoply of important social goals. The adversarial model assumes we are more likely to uncover the truth about a contested event as the result of the efforts of the parties who have a self-interest in the discovery of proof and exposing the frailties of an opponent’s proof than from the efforts of a judge charged only with an official duty to investigate the case (Hazard, Fleming, and Levesdorf 1992). The adversarial model also assumes that the parties’ participation in the investigation and telling of their story, and the use of a decision maker who is independent of the investigation of the case, will enhance support of the judicial system and confidence in its decisions (Tyler 1992). The model is also touted as an essential ingredient of our American democracy. The American legal system’s extensive use of the jury system and its faith in the competence of jurors to resolve complex questions is based on a belief in the wisdom of common men and women, incorporation of community values into the trial system, and democratic values imbued by trusting governmental action to private citizens (Lempert 1981).

The rules that implement the adversarial model incorporate these goals and illuminate some of the fundamental tensions they present. Con-

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sider the rule describing the goals of the Federal Rules of Evidence, which govern the admissibility of evidence at trial in the federal courts: "These rules shall be construed to secure fairness in administration, elimination of unjustifiable expense and delay, and promotion of growth and development of the law of evidence to the end that the truth may be ascertained and proceedings justly determined" (Federal Rules of Evidence Rule 102). Securing fairness, avoiding unjustifiable expense and delay, ascertaining truth, and justly determining proceedings are important but not invariably consonant goals. For example, the cost of ascertaining truth in some cases may be beyond the means of the parties or require a significant delay that prevents the speedy resolution of criminal charges or civil claims. Thus the rules recognize truth as an important, concurrent goal of the adversary system.

The adversary system has long recognized, as an important component of our democratic tradition, the wisdom of identifying the witness's bias and prejudice as well as the decision maker's. The adversarial model assumes that the believability of all witnesses, both lay and expert, is affected by their values and beliefs, and rejects the notion that impartiality or neutrality exists. Nonetheless, the use of partisan rather than court-appointed experts has been the subject of much intense criticism (Champane et al. 2001).

One criticism of the adversary system claims that the information presented to the courts by privately retained experts is biased because attorneys seek out experts who will best assist their case and not necessarily because the experts represent mainstream science. A related criticism claims that the use of retained experts provides judges little control over the use of nonmainstream experts. Critics also claim that the use of privately retained experts increases the number of experts and therefore the expense of using experts. And critics claim that a system in which retention turns on the support an expert may provide for the case is a built-in incentive for experts' opinions to accommodate the interests of their attorney-employers. Notwithstanding these criticisms and the authority that courts enjoy to appoint experts, the use of court-appointed experts is exceptional in the American judicial system.

The U.S. legal system's failure to embrace the use of court-appointed experts as a panacea for the ills of retained experts is rooted, in large part, in its skepticism that experts' biases and prejudices are solely a product of the adversary system. "It is slightly mysterious that it should be thought that experts are venal mountebanks when engaged by the parties but transformed into paragons of objectivity when employed by the

courts” (Howard 1991: 101; Champagne, Shuman, and Whitaker 1996). Thus, as science has wrestled with the way in which history, training, and values have bounded scientific knowledge (Kuhn 1970), the American adversary model has wrestled with proposals that would place the search for truth in the hands of scientists in science courts or other procedures that may not adequately expose the scientist’s values and beliefs (Jacobs 1993). Wary that “there is no such thing as a neutral, impartial witness” (Diamond 1959: 229–230), the adversarial model has regarded the role of the jury and rules of admissibility that encourage informing the jury of all relevant evidence as critical to ascertaining truth and justly determining proceedings (Thayer 1898).

The role of the judge, jury, lawyers, and experts is central to the operation of the adversarial model. The adversarial model assumes that the parties’ lawyers will be skilled, zealous advocates who drive the system investigating and presenting favorable evidence and challenging unfavorable evidence. Unlike the inquisitorial model, in the traditional adversary model the judge is not expected to conduct an independent investigation and determine the evidence that will be used to decide the case, but is instead expected to ensure that the procedures are fair and the parties have an equivalent opportunity to gather evidence and present their case. Although there is great ambivalence about the competence and biases of juries in legal and popular culture (Shuman and Champagne 1997), the traditional adversarial model relies on the intelligence and common sense of the jury, as reflected in this statement from the Supreme Court’s 1983 opinion refusing to exclude psychiatric testimony in a capital sentencing proceeding labeled unreliable by the American Psychiatric Association: “Petitioner’s entire argument . . . is founded on the premise that a jury will not be able to separate the wheat from the chaff. We do not share in this low evaluation of the adversary process” (*Barefoot v. Estelle*, 463 U.S. 880, 901 n.7 [1983]). (As we shall see below, one of the critical differences in the gatekeeper model is its rejection of this faith in the abilities of juries.) Experts are expected to play a useful, partisan role in the adversarial model, as reflected in another Supreme Court opinion recognizing the defendant’s constitutional right to the appointment of a psychiatrist to assist his attorney in the presentation of an insanity defense. “Without the assistance of a psychiatrist to conduct a professional examination on issues relevant to the defense, to help determine whether the insanity defense is viable, to present testimony, and to assist in preparing the cross-examination of a State’s psychiatric witnesses, the risk of an inaccurate resolution of sanity issues is extremely

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high. With such assistance, the defendant is fairly able to present at least enough information to the jury, in a meaningful manner, as to permit it to make a sensible determination” (Ake v. Oklahoma, 470 U.S. 68, 82 [1985]).

The traditional adversarial model has relied heavily on the jury to decide the ultimate issues in the case. It zealously guarded the jury’s prerogative by excluding expert testimony when the issues were not “beyond the ken” of the jury or when the expert testimony threatened to usurp the function of the jury, criteria that have been relaxed in recent years. When expert testimony is admissible on an issue, the requirements for admissibility under the traditional adversary approach focus predominantly on the qualifications of the expert, leaving scrutiny of the validity of the expert’s methods and procedures to the fact finder as part of its assessment of the appropriate weight to be accorded the evidence in reaching a decision on the ultimate issues. The standard applied in assessing qualifications is a functional determination to which the trial judge is accorded significant discretion. So, in assessing the qualifications of a physician to testify as an expert, the standard typical of the adversarial approach notes:

An expert need not have certificates of training, nor memberships in professional organizations. . . . Nor need he be . . . an outstanding practitioner in the field in which he professes expertise. Comparisons between his professional stature and the stature of witnesses for an opposing party may be made by the jury. . . . the only question for the trial judge who must decide whether or not to allow the jury to consider a proffered expert’s opinions is, “whether his knowledge of the subject matter is such that his opinion will most likely assist the trier of fact in arriving at the truth.” (United States v. Barker, 553 F.2d 1013, 1024 [6th Cir. 1977])

Under the traditional adversarial model, once having determined that the expert is qualified, it is rare for the court to engage in a searching analysis of the expert’s expertise in determining admissibility (Eymard v. Pan American World Airways, 795 F.2d 1230 [5th Cir. 1986]). Only when the expert has sought to present novel sources of expertise, purportedly grounded in science, have courts applied more rigorous threshold scrutiny as a prerequisite to admissibility (Frye v. United States, 293 F. 1013 [D.C. Cir. 1923]). Articulating the approach that characterizes the traditional adversarial model, the Supreme Court noted that “the rules of evidence generally extant at the federal and state levels anticipate that

relevant, unprivileged evidence should be admitted and its weight left to the factfinder, who would have the benefit of cross-examination and contrary evidence by the opposing party” (Barefoot v. Estelle, 463 U.S. at 898). Under this approach, medical expert testimony in medical malpractice or personal injury cases has rarely invoked threshold scrutiny beyond determining the witness’s qualifications, the basis for the opinion, or the confidence with which it was expressed (Black 1988).

Although clinical practice guidelines and science-based medical evidence are not synonymous, clinical practice guidelines are the most common manifestation of science-based medical evidence with which courts have dealt. The absence of reported decisions addressing the admissibility of practice guidelines suggests that lawyers and judges have assessed expert testimony offering science-based medical evidence from the perspective of the traditional adversarial model. Although practice guidelines play an active role in medical malpractice litigation (Hyams, Shapiro, and Brennan 1996), the reported decisions reflect that lawyers and judges have not regarded the guideline’s validity as an expert or scientific evidence admissibility issue. “Without much fanfare, litigants have introduced and courts have approved the use of practice guidelines to provide evidence of the relevant standard of care” (Shuman 1997a: 104).

In a negligence action, in the absence of an analysis of negligence in which a statute or regulation defines the standard of care (e.g., exceeding the posted speed limit), the jury is charged with determining what society is entitled to expect of an actor under the circumstances (i.e., the behavior of the proverbial reasonable person). From the perspective of the adversary model, whether guidelines are “quality enhancing” or “cost-reducing” (Brennan 1991), they may provide the fact finder with important information about customary practice, the practice of a respectable minority, reasonable prudence, or acceptable practice, to consider in its determination of reasonableness under the circumstances (Rosoff 1995; Havighurst 1991).

Legislatures and courts have yet to determine how triers-of-fact should use practice guidelines. They can be extremely helpful in cases calling into question whether a physician chose the wrong course of diagnosis or treatment or should have gone further in attempting to understand or correct the situation. . . . However, they should not necessarily be viewed as conclusive evidence of the standard of care. Proof of compliance with practice guidelines should not necessarily establish due

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care; just as proof of noncompliance should not establish negligence per se. Clinical practice guidelines can materially assist the triers-of-fact in medical malpractice cases. Properly authenticated clinical practice guidelines are relevant to the question of the proper standard of care and should be admitted as substantive evidence if introduced through a witness who can lay a proper foundation. (*Frakes v. Cardiology Consultants*, No. 01-A-01-9702-CV-0069, 1997 Tenn. App. LEXIS 597, at *15–16 [Tenn. App. Aug. 29, 1997])¹

Courts relying on the adversarial model have not engaged in demanding scrutiny of the admissibility of science-based medical evidence. Rather, they have regarded it as important feature of the adversary model to provide all such relevant information to the jury, who, with the benefit of competent counsel's rigorous cross-examination and presentation of opposing expert evidence, can assess the reliability of this evidence and give it the appropriate weight in their determination.

The Gatekeeping Approach

The gatekeeping approach to the admission of expert testimony rests on the belief that the traditional adversary model has not worked well in scrutinizing expert testimony. Its critique of the operation of the traditional adversary model is that many judges have been unwilling or unable to exclude unreliable claims of expertise (Angell 1996); that there are large numbers of experts willing to offer testimony that would not satisfy the standards for work in their profession's laboratories, clinics, or journals;² that attorneys operating under the ethos of the adversary system

1. See also *Lowry v. Henry Mayo Newhall Memorial Hospital* (229 Cal. Rptr. 620, 621–22 [Cal App. 1986] ["Plaintiffs charged that defendant acted in bad faith by arbitrarily deviating from the American Heart Association guidelines for advanced cardiac life support by administering the drug Atropine rather than Epinephrine. Plaintiffs argued that had Epinephrine been administered instead of Atropine, decedent's chances of survival would have dramatically increased. . . . In reply, defendant directed the court to deposition testimony excerpts in which she explained that the American Heart Association guidelines are mere guidelines that may be altered by the physician. She explained that she administered Atropine because it is one of the drugs used as a first line to start the heart after the monitor reveals that there is no cardiac activity. This evidence was unrefuted."]).

2. Note the following, from the case of *Eymand v. Pan American Airways* (795 F.2d 1230, 1233–34 [5th Cir. 1986]):

First, many experts are members of the academic community who supplement their teaching salaries with consulting work. We know from our judicial experience that many such able persons present studies and express opinions that they might not be willing to express in an article submitted to a refereed journal of their discipline or in other contexts subject to peer review. We think that is one important signal, along with many others, that ought to be con-

have sought experts to support their case without regard to their professional competence;³ that jurors lacking scientific or technical expertise have relied on irrational, superficial criteria to assess the believability of experts;⁴ and, accordingly, heightened scrutiny of the admissibility of expert testimony is necessary (Huber 1991).

In contrast with the traditional adversarial approach, the gatekeeping approach assumes that it is appropriate for the judge to impose a demanding standard of scrutiny for the admissibility of expert testimony, and given doubts about the abilities of juries that characterize the gatekeeping model, the role of the jury in assessing the reliability of expert testimony is more circumscribed. Similarly, the gatekeeping approach assumes that the role of lawyers in trying cases, and the role of experts in presenting evidence, will be more circumscribed than under the traditional adversarial model.

Although the gatekeeper model calls for raising the threshold for admitting expert testimony, those calls have been directed at standards for assessing the reliability of the expert's methods and procedures, not the expert's qualifications. Even in courts that have embraced the gatekeeper model, the standard for scrutiny of the expert's qualifications is unchanged from the traditional adversary model. It remains a functional analysis of the expert's ability to provide relevant evidence on the issue for which the expert is offered. "What is required is that the offering party establish that the expert has 'knowledge, skill, experience, training,

sidered in deciding whether to accept expert testimony. Second, the professional expert is now commonplace. That a person spends substantially all of his time consulting with attorneys and testifying is not a disqualification. But experts whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an "expert." . . . [W]e take this occasion to caution that the standard leaves appellate judges with a considerable task. We will turn to that task with a sharp eye, particularly in those instances, hopefully few, where the record makes it evident that the decision to receive expert testimony was simply tossed off to the jury under a "let it all in" philosophy. Our message to our able trial colleagues: it is time to take hold of expert testimony in federal trials.

See also Hagen 1997.

3. "Modern trial lawyers, the critics claim, hire articulate pseudo-experts from the burgeoning ranks of full-time scientific actors unleashed by the growth of the expert witness industry" (Jacobs 1993: 1092).

4. Although the rationale for this criticism of jury decision making capacity is rarely set forth explicitly in its entirety, pieced together its reasoning is as follows. First, experts testify to scientific, technical, or other specialized knowledge with which jurors, not chosen because they possess any specialized knowledge, are unlikely to be familiar. Second, jurors, unlike judges, are not generally worldly, well educated, and trained in rigorous analytical skills necessary to assess critically the new, unfamiliar information that experts present. Third, lacking the requisite worldliness, education, and analytical skills, jurors resort to irrational decision-making strategies to determine whether to believe an expert, that rely on considerations such as the expert's appearance, personality, or presentation style (Shuman and Champagne 1997: 251–252).

or education' regarding the specific issue before the court which would qualify the expert to give an opinion on that particular subject" (Broders v. Heise, 924 S.W.2d 148, 153 [Tex. 1996]).

One barrier that stands in the way of changing this approach for the scrutiny of medical experts' qualifications is the absence of relevant, comprehensive, and authoritative credentialing criteria. Where would courts turn for guidance? There are no federal or state rules or regulations enumerating an exhaustive list of medical procedures and the qualifications required to perform them, let alone privately promulgated guidelines. And the standard of review continues to leave the issue to the discretion of the trial court.⁵

The gatekeeper model articulated in the Supreme Court's recent trilogy on the admissibility of expert testimony under the Federal Rules of Evidence—*Daubert v. Merrell Dow Pharmaceuticals* (509 U.S. 579 [1993]), *General Electric Co. v. Joiner* (522 U.S. 136 [1997]), and *Kumho Tire Co. v. Carmichael* (526 U.S. 137 [1999])—places on the trial court judge "the task of ensuring that an expert's testimony rests on a reliable foundation and is relevant to the task at hand" (*Daubert*, 509 U.S. at 597). Rejecting the federal rules' incorporation of the *Frye* "general acceptance"⁶ test that relied on consensus to assess the admissibility of novel scientific evidence, the *Daubert* Court constructed a standard built on the work of Karl Popper (1989; see also Susan Haack in this issue),

5. "We have held that abuse of discretion is the proper standard of review of a district court's evidentiary rulings. . . . Indeed, our cases on the subject go back as far as *Spring Co. v. Edgar*, 99 U.S. 645, 658, 25 L. Ed. 487 (1879), where we said that 'cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly erroneous.' The Court of Appeals suggested that *Daubert* somehow altered this general rule in the context of a district court's decision to exclude scientific evidence. But *Daubert* did not address the standard of appellate review for evidentiary rulings at all" (*General Electric Co. v. Joiner*, 522 U.S. 136, 140 [1997]).

6. *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), a 1923 decision of the District of Columbia Court of Appeals addressing the admissibility of a precursor of the polygraph, articulated a test that came to be accepted as the standard for the admissibility of novel scientific evidence in many state and federal courts:

The rule is that the opinions of experts or skilled witnesses are admissible in evidence in those cases in which the matter of inquiry is such that inexperienced persons are unlikely to prove capable of forming a correct judgment upon it, for the reason that the subject-matter so far partakes of a science, art, or trade as to require a previous habit or experience or study in it, in order to acquire a knowledge of it. When the question involved does not lie within the range of common experience or common knowledge, but requires special experience or special knowledge, then the opinions of witnesses skilled in that particular science, art, or trade to which the question relates are admissible in evidence. (*Frye*, 293 F. at 1014)

Frye's critics complained that it was impracticable and did not directly address the quality of the science. In the face of this criticism, the failure of the Federal Rules of Evidence to address the continued viability of *Frye* led to a split in the federal circuits and ultimately to the *Daubert* decision resolving the issue.

which relies on *falsifiability* as the hallmark of the scientific enterprise, considering:

Whether a “theory or technique . . . can be (and has been) tested”;

Whether it “has been subjected to peer review and publication”;

Whether, in respect to a particular technique, there is a high “known or potential rate of error” and whether there are “standards controlling the technique’s operation”; and

Whether the theory or technique enjoys “general acceptance” within a “relevant scientific community.” (*Daubert*, 509 U.S. at 593–594)

Joiner clarified that appellate courts reviewing trial court decisions under *Daubert* are to reverse only when the trial court abused its discretion (i.e., failed to use sound legal reasoning), a standard that has traditionally granted wide latitude to the decisions of the trial court. And *Kumho Tire* clarified that the *Daubert* criteria applied to all proposed expert testimony, whether grounded in scientific, technical, or other specialized knowledge, but “whether *Daubert*’s specific factors are, or are not, reasonable measures of reliability in a particular case is a matter that the law grants the trial judge broad latitude to determine” (*Kumho Tire*, 526 U.S. at 153).

The *Daubert*, *Joiner*, *Kumho Tire* trilogy has important implications for science-based medical evidence. If judges are required to act as gatekeepers so that juries hear only relevant and reliable expert testimony, then only expertise derived from asking “What’s the evidence” (Eisenberg 1999: 1869) should satisfy the admissibility threshold for claims of medical expertise. If it is not acceptable to admit an expert’s conclusion, “just because somebody with a diploma says it is so” (United States v. Ingham, 42 M.J. 218, 226 [A.C.M.R. 1995]), then asking about testability, peer review and publication, error rates, and acceptance within the relevant scientific community of the expert’s methods and procedures are sensible requisites for claims of medical expertise in the courts as well as in medical practice. How various practice guidelines would fare under that analysis, let alone what currently accepted claims of medical expertise meet that threshold, would present an interesting study.

Much Ado about Little: The Effect of *Daubert*, *Joiner*, and *Kumho Tire* on Claims of Medical Expertise

Although *Daubert* arose in the context of a toxic tort claim assessing proffered biomedical evidence, the interpretation of the Federal Rules of

Evidence it announced was not explicitly limited to natural science evidence. *Joiner* and *Kumho Tire* formally extended *Daubert*'s application to all expert testimony in the federal courts and the state courts that have chosen to follow them. In the courts in which it applies, does *Daubert* require that medical experts pass a rigorous test of the reliability of their methods and procedures as a condition of admissibility? The answer, at least as reflected in the skewed sample represented by reported decisions (largely appellate cases), is that except in certain contexts, the admissibility of medical expert testimony after *Daubert* looks much like the admissibility of medical expert testimony before *Daubert*.

Notwithstanding the call for courts to address claims of medical expertise more rigorously under *Daubert*, subsequent case law does not reflect that this potential has been realized. As noted above, the reported cases do not reveal opinions scrutinizing the admissibility of "practice guidelines" or science-based medical evidence under *Daubert*. Indeed, some courts have implied that it is not their task to address such issues. "*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance. It demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion" (*DiPetrillo v. Dow Chemical Co.*, 729 A.2d 677, 690 [R.I. 1999]). Specifically in the context of guidelines, courts have given no hint that different guidelines offered as competing evidence of appropriate practice should be kept from the fact finder.

The evidence shows that reasonable, reputable medical experts do not agree on how often routine mammograms should be performed. The American Cancer Society recommends yearly mammography, while the American College of Obstetricians and Gynecologists recommends "regular" mammography without specifying frequency. If the evidence supports a conclusion that the doctor's only negligence was failure to perform a routine mammogram, then the two schools of thought instruction is appropriate. (*Levine v. Rosen*, 575 A.2d 579, 582 [Pa. Super. Ct. 1990])

Some, including Chief Justice William H. Rehnquist, question the ability of trial court judges to engage in the *Daubert* analysis. "I defer to no one in my confidence in federal judges; but I am at a loss to know what is meant when it is said that the scientific status of a theory depends on its 'falsifiability,' and I suspect some of them will be, too" (*Daubert*, 509 U.S. at 600 [Rehnquist, C.J., concurring and dissenting]). While there is

anecdotal evidence of impressive judicial scrutiny of expert testimony applying *Daubert* as well as anecdotal evidence of less than impressive scrutiny, we have no data for a systemic assessment of the way in which judges have dealt with the issue or what assistance might benefit them. An important step in addressing judicial scrutiny of medical expertise would be a study of this decision-making process in the trial courts.

Civil Litigation

One area of civil litigation in which there has been a clear and consistent change in the admissibility of medical experts in the wake of *Daubert* is in toxic tort and products liability cases (Finley 1999). The threshold for the admissibility of medical as well as other types of expertise has risen significantly in this class of cases. *Daubert* itself aptly illustrates that in these cases being qualified as an expert is no longer an assurance that an expert's testimony will be deemed sufficiently reliable to be admissible. The plaintiff's experts in *Daubert*, whose testimony was ultimately rejected as unreliable by the court of appeals applying the Supreme Court's new criteria (*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 [9th Cir. 1995]), included:

Shanna Helen Swan, who received a master's degree in biostatistics from Columbia University and a doctorate in statistics from the University of California at Berkeley, is chief of the section of the California Department of Health and Services that determines causes of birth defects and has served as a consultant to the World Health Organization, the Food and Drug Administration, and the National Institutes of Health. . . . Stuart A. Newman, who received his bachelor's degree in chemistry from Columbia University and his master's and doctorate in chemistry from the University of Chicago, is a professor at New York Medical College and has spent over a decade studying the effect of chemicals on limb development. . . . The credentials of the others are similarly impressive. (*Daubert*, 509 U.S. at 583 n.2)

At least in this class of cases, qualifications are no longer a guarantee that the expert's testimony will be deemed sufficiently reliable to be considered by the fact finder.

In medical malpractice litigation, however, the impact of *Daubert* appears to be more limited. The *Frye* "general acceptance" gatekeeping test that preceded *Daubert* had not been regularly applied to expert testimony in medical malpractice cases (Black 1986). Instead, applying the

traditional adversarial approach, once the expert was determined to be qualified, the reliability of the expert's methods and procedures was typically left to the jury. Critics of medical malpractice litigation expressed optimism that *Daubert* would eliminate unreliable expert testimony in these cases (McAbee 1995).

From the few reported cases addressing *Daubert*'s application to standard-of-care issues in medical malpractice cases, no clear pattern of more rigorous scrutiny emerges. Two reported decisions reject outright *Daubert*'s application to standard-of-care issues in medical malpractice cases. The Supreme Court of Montana chose to apply *Daubert* only to novel scientific evidence and therefore held that it does not apply to the qualification of a physician as an expert on the information that a physician should provide to a patient to obtain informed consent (*Gilkey v. Schweitzer*, 983 P.2d 869 [Mont. 1999]). The Supreme Court of Washington rejected *Daubert*'s application, holding that a conventional analysis under the rules of evidence was more appropriate because the expert's medical opinion was based on practical experience and acquired knowledge, not a novel scientific procedure (*Reese v. Stroh*, 907 P.2d 282, 286 [Wash. 1995]). In two other standard-of-care decisions citing *Daubert*, appellate courts concluded that the trial court had not abused its discretion in the expert testimony it admitted on the standard of care: *Carroll v. Morgan* (17 F.3d 787 [5th Cir. 1994] [trial court did not abuse discretion under *Daubert* in refusing to exclude defense expert in medical malpractice case who "refused to recognize any medical textbooks or journal articles as authoritative on endocarditis"]) and *Mitchell v. United States* (141 F.3d 8 [1st Cir. 1998] [trial court did not abuse discretion under *Daubert* in admitting expert testimony in medical malpractice case by qualified experts on the standard of care just because witness was not specialist in field in which he gave opinion]). There is little sign that *Daubert* challenges to admitting expert testimony on the standard of care in medical malpractice cases are likely to be successful so long as lawyers and judges accept testimony as to customary practice⁷ without demand-

7. Section 11 of the 1999 discussion draft *Restatement (Third) of Torts: General Principles*, focuses on *custom*. That discussion includes the following:

(a) The actor's compliance with the custom of the community, or of others in like circumstances, is evidence that the actor's conduct is not negligent, but does not preclude a finding of negligence.

and

(b) The actor's departure from the custom of the community, or of others in like circumstances, in a way that increases risks is evidence of the actor's negligence but does not require a finding of negligence.

ing methodologically sound survey evidence of its adoption, let alone rigorous proof of efficacy.⁸ The absence of more demanding threshold scrutiny on this issue appears to result, in large part, from a desire by all parties to enjoy flexibility in framing their cases. Only a mutual willingness to limit that flexibility will result in raising the threshold.

Because the question of causation presents issues that clearly appear to be grounded in science, it might be expected that *Daubert* would have a more profound effect on causation issues in medical malpractice cases. If *Daubert* has had any effect on causation issues in reported decisions in medical malpractice cases, it is modest. In two reported medical malpractice cases, appellate courts found that trial courts had abused their discretion in excluding testimony on causation under *Daubert*.⁹ Another reported case concluded that there was no abuse of discretion in excluding expert testimony on causation under *Daubert* in a medical malpractice case (*North Dallas Diagnostic Center v. Dewberry*, 900 S.W.2d 90 [Tex. Civ. App. 1995]), but another court concluded that there was an abuse of discretion in admitting expert testimony on causation under *Daubert* in a medical malpractice case (*Tanner v. Westbrook*, 174 F.3d 542 [5th Cir. 1999]). However, it is far from clear that the decisions relying on *Daubert* to support exclusion would have reached a different result before that decision (*Checchio v. Frankford Hospital*, 35 Phila. 53, 35 Pa. D. & C.4th 143 [1998]).

In other categories of civil cases in which psychiatric testimony is frequently presented, such as family law and probate proceedings, there is little indication in the reported cases that *Daubert* has changed the stan-

8. According to Section 4 of the 1999 discussion draft of *Restatement (Third) of Torts: General Principles*,

An actor is negligent in engaging in conduct if the actor does not exercise reasonable care under all the circumstances. Primary factors to consider in ascertaining whether conduct lacks reasonable care are the foreseeable likelihood that it will result in harm, the foreseeable severity of the harm that may ensue, and the burden that would be borne by the actor and others if the actor takes precautions that eliminate or reduce the possibility of harm.

Comments:

d. Explanation. Insofar as this section identifies the primary factors for ascertaining negligence, it can be said to set forth a “risk-benefit test” for negligence, where the “risk” is the overall magnitude of the risk created by the actor’s conduct and the “benefit” is the advantages that the actor or others gain if the actor refrains from risk prevention measures.

9. *Bunting v. Jamieson*, 984 P.2d 467 (Wyo. 1999) (trial court abused discretion in excluding expert testimony of physician on causation issue in medical malpractice case based upon judgment of failure to satisfy *Daubert* “peer review” factor); *Williams v. Hedicar*, 561 N.W.2d 817 (Iowa 1997) (trial court abused discretion under *Daubert* in medical malpractice case in excluding expert’s testimony that defendant’s negligence in failing to treat pregnant woman for chicken pox resulted in child being born blind in one eye. “We do not accept the proposition that statistical proof has to be presented before a medical expert can testify on causation.”).

dard for the admissibility of medical experts (Frolik 1999; Shuman 1997b).

Criminal Litigation

The three cases in which the Supreme Court chose to grant discretionary review to make pronouncements about the trial court's role as a gatekeeper in the admissibility of expert testimony under the Federal Rules of Evidence—*Daubert*, *Joiner*, and *Kumho Tire*—are all civil cases that arise out of toxic tort or products liability claims. A decade before *Daubert*, the Supreme Court had decided *Barefoot v. Estelle* (463 U.S. 880 [1983]), a constitutional challenge to the admissibility of psychiatric prediction testimony in a state court capital sentencing proceeding. Embracing a simple relevance standard, *Barefoot* permitted the introduction of psychiatric testimony labeled unreliable by the expert's peers, the American Psychiatric Association. *Daubert*, *Joiner*, and *Kumho Tire* neither distinguish *Barefoot* nor limit its application, leaving one to ponder whether they were intended to be applied to criminal litigation. Indeed, the Court's two other decisions involving expert testimony in criminal litigation—*Rock v. Arkansas* (483 U.S. 44 [1987] [rejecting state rule prohibiting admission of defendant's hypnotically refreshed testimony as a violation of the defendant's constitutional right to testify]) and *United States v. Scheffer* (523 U.S. 303 [1998] [Military Rule of Evidence excluding polygraph evidence in court-martial proceedings did not violate defendant's constitutional right to present defense])—have not been a core concern of the *Daubert*, *Joiner*, and *Kumho Tire* trilogy.

Although it might be thought at least as important to avoid erroneous capital punishment or lengthy incarceration as it is to avoid erroneous wealth redistribution, “the ‘junk science’ debate has all but ignored criminal prosecutions” (Giannelli 1993: 130). There are particular judges (e.g., Judge Jack Weinstein's decisions in *United States v. Gigante*, 996 F. Supp. 194 [E.D.N.Y. 1997], and *United States v. Shonubi*, 895 F. Supp. 460 [E.D.N.Y. 1995]) and particular categories of evidence (e.g., *State v. Hungerford*, 697 A.2d 916 [N.H. 1997] [repressed memory of child sexual abuse claims]) that have yielded demanding scrutiny of medical expertise in criminal cases. However, in the main, it is business as usual for the admission of medical experts in criminal cases after *Daubert*.

There are no reported *Daubert* challenges to retrospective psychiatric assessments of criminal responsibility (i.e., the reliability of the methods and procedures used to assess the mental state of a criminal defendant at

a time long before the defendant was examined) (Shuman 1996). In addressing the admissibility of expert medical testimony as to cause of death in homicide prosecution, courts ignore the lesson of *Daubert* and equate the expert's qualifications with the reliability of the expert's methods and procedures.¹⁰ Psychiatric prediction of future violence in capital sentencing unsupported by the research continues to be admitted after *Daubert* (Faigman 1995).

Barriers to a More Informed Application of Science-Based Medical Evidence in Law

Why has the potential that many viewed *Daubert* to offer not been realized? Specifically what barriers exist to a more informed application of science-based medical evidence in the law? The answer is to be found in core aspects of legal practice and theory. Although *Daubert*, *Joiner*, and *Kumho Tire* may reflect a change in attitude about the trial of toxic tort and products liability actions, they have not changed fundamental attitudes about the admissibility of expert testimony across the legal system for important pragmatic and philosophical reasons.

Pragmatically, the temporal distinctions between law and science that have posed difficult problems for the legal system remain. Indeed, they may be exacerbated by the *Daubert* trilogy. The legal system's temporal constraints for resolving criminal charges against defendants who may be confined prior to trial or civil compensation claims made by seriously injured plaintiffs are different from the temporal constraints on scientists. "Courts typically do not have the luxury of holding their decisions in abeyance until a body of research develops" (Shuman and Sales 1998: 1247). *Daubert's* command that courts take science seriously also has temporal consequences. Rigorous independent judicial review of the reliability of the expert's methods and procedures demands more time from an overburdened judiciary. Moreover, it demands a set of skills that are neither required of those who enter the legal profession nor taught as a required part of the law school curriculum.

10. "We find no merit to Sippio's assertion that Dr. Smialek's expertise as a forensic pathologist did not qualify him to render an opinion as to manner of death. Dr. Smialek was qualified as an expert in forensic pathology without challenge by the defense. Moreover, Dr. Smialek explained that forensic pathologists are 'trained to recognize certain patterns of injury and [have] to be familiar with gunshot wounds . . . so that [they] can render a proper diagnosis in an attempt to reconstruct the events surrounding the sudden death of an individual.' His testimony as to manner of death was, therefore, consistent with his extensive medical training and professional experiences" (Sippio v. State, 714 A.2d 864, 872 [Md. 1998]).

Lawyers have realized that the same arguments that can be made to exclude their opponent's experts can often be made against their own experts. In some cases, such as family law, lawyers do not typically represent only husbands or wives, plaintiffs or defendants, thus next week they may seek to admit the testimony they challenge today. In other cases where lawyers' roles do not change as readily, such as criminal prosecutions and personal injury litigation, the methods and procedures employed by all of the experts are often surprisingly similar. Thus many lawyers have chosen to attack the credibility of the opposing expert's testimony on cross-examination rather than seeking a ruling that might ultimately result in the exclusion of their own experts. Indeed, in some instances an effective cross-examination of an expert who has utilized an unreliable methodology may be tactically preferable to exclusion of the testimony in its entirety.

Philosophically, many judges have resisted implementation of *Daubert* as an ill-conceived attempt to reshape the adversary system and the role of the jury in it:

I do not think there is so much of a problem between what was *Frye* and what is *Daubert*, but I think *Daubert* has brought a name to the monster that has really . . . changed the balance of what does and does not go to the jury. That is really troubling to me, to have the gatekeeper be able to say, 'The jury is not even going to get to hear this.' It seems to me to really fundamentally change our whole court system. (Roscoe Pound Foundation 1998: 89)

We have to consider ourselves protectors of the jury system, not guardians for the scientific community and their temporal visions of scientific purity. (Ibid.: 31)

Others have seen the call for a higher admissibility threshold as a problem for the right of litigants, particularly criminal defendants,¹¹ to tell their story that raises constitutional fairness concerns (Slobogin 1998). While still others have argued that although the rules that raise the threshold for the admissibility of expert testimony are facially neutral, they discriminate against certain classes of litigants. For example, by increasing the number and kinds of experts who must be presented to sat-

11. "Courts, as gatekeepers, must be aware of how difficult it can be for some parties—particularly indigent criminal defendants—to obtain an expert to testify. The fact that one side may lack adequate resources with which to fully develop its case is a constant problem" (Weinstein 1998: 1008).

isfy a *Daubert* challenge, requiring not only clinicians who perform diagnostic procedures but researchers who can validate these procedures (Jesionowski v. Beck, 955 F. Supp. 149 [D. Mass. 1997]), *Daubert* increases the cost of litigation, privileging wealthier litigants over poorer litigants, corporations over individuals.

Daubert has not so much changed attitudes about the adversary model as it has reflected one segment of society's long festering dissatisfaction with it, which may explain why the *Daubert* trilogy has not precipitated a radical transformation of the trial process. For the most part, attitudes about fairness, justice, the adversary system, and use of juries have remained unchanged, so that what appellate courts viewed as a change in the standard for admissibility is often translated in the trial courts into a debate about what weight the jury should give to the evidence.

This experience parallels proposals for the use of court-appointed experts. Although proposals for use of court-appointed experts have long been touted as a solution to problems with retained experts, they have not seen widespread utilization. In the most comprehensive study to date, Joe S. Cecil and Thomas E. Willging (1993) found that court-appointed experts were infrequently used in the federal courts, based in part on the judges' concerns with the potential for interference with the adversary system.

Where Do We Go from Here? Constraints and Concerns

The problems raised in this article are not new, nor is the array of solutions often proposed. Simply reiterating those proposals, such as higher admissibility thresholds and greater use of court-appointed experts, without addressing the reasons for resistance to change, is unlikely to produce a more informed judicial response to claims of expertise in medicine and health care.

There is a widely held perception that raising the reliability threshold for the admissibility of expert testimony is not so much about evidence reform as it is about tort reform, raising barriers for tort plaintiffs (Finley 1999). Apart from undercutting confidence in the impartiality of the judicial process, the decisions that provide support for this perception of a result-oriented jurisprudence undermine the importance of science-based medical evidence for the courts. They suggest that judicial assessments of the science underlying medical expertise matters in some but not all contexts. Any credible attempt to produce a more informed judi-

cial response to claims of medical expertise must address expertise in medicine and health care consistently across the legal spectrum. Reserving rigorous scrutiny of the reliability of medical expertise to narrow classes of cases makes for bad science and bad law.

Many of the problems that courts face in assessing medical expertise are the inevitable result of substantive legal standards. For example, fault-based compensation rules coupled with an absence of national health care or a broad-based social safety net encourages seriously injured individuals to blame others for their injuries to obtain needed financial assistance, guaranteeing that courts will be faced with complex scientific questions for which timely answers will often not exist. Substantive legal standards that call for medical expertise on issues that cannot be operationalized for rigorous study (e.g., the best interests of the child) lead to nonfalsifiable claims of expertise (Shuman 1997b). Any practicable attempt to produce a more informed judicial response to claims of medical expertise must also address the substantive law that often creates a false dichotomy requiring a choice between science and justice. The quality of the answers medical experts provide turns, invariably, on how the legal system frames the questions it asks of experts.

There are many examples of judges' and lawyers' sophisticated applications of *Daubert* and its state court analogues. There are also many cases that raise important scientific issues in which judges and lawyers either misunderstand the science or avoid the issue and resolve the case on some other legal basis. One apparent explanation for the difference is the education in science that judges and lawyers possess. Any viable attempt to produce a more informed judicial response to claims of medical expertise entails integrating science education into the legal education process, not as an alternative method of satisfying continuing education requirements but as a core aspect of legal education. If lawyers and judges are to be expected to take science seriously, science must be taken seriously in legal education.

Finally, many who advance the gatekeeper model argue that the jury's incapacity to sort out unreliable science necessitates a more rigid threshold for admissibility, while many who oppose this approach do so exactly because they see it as an assault on the right to jury trial. The jury system is fundamental to our democracy by institutionalizing the role of the citizenry in the legal process. It is both unwise and unnecessary to force a confrontation between science and democracy. Any acceptable solutions to assessing claims of medical expertise must include mechanisms

for enhancing the reliability of expert testimony without denigrating the jury system.

Conclusion

Ongoing development of medicine as a scientifically grounded practice reveals that the medical profession shares much with the legal profession. Science-based medical evidence and the *Daubert* trilogy reflect unorchestrated parallel movements in medicine and law about how to assess expertise critically. Although neither has paid any attention to the other, both movements recognize that professional education and training are necessary but not sufficient to assure expertise. Expertise, in the vision of both science-based medical evidence and the *Daubert* trilogy, begins but does not end with the question of qualifications. A medical expert's qualifications provides no assurance of the reliability of the expert's methods and procedures. Beyond both professions independently drawing this distinction, the impact of distinguishing qualifications and expertise in medicine and law is also of consequence. Why has the recognition of this distinction not transformed the practice of medicine or law?

Science-based medical evidence and the *Daubert* trilogy reveal much about the nature of both professions. Just as the promulgation of myriad clinical practice guidelines that claim to rest on a critical examination of the medical research literature has not precipitated a sea change in medical practice, so the *Daubert* trilogy's pronouncements about the admissibility of expert testimony that claims to rest on a critical examination of expertise has not precipitated a sea change in legal practice. The attitudes and beliefs of attorneys about the conduct of trials have not been fundamentally changed overnight by the *Daubert* trilogy any more than the attitudes and beliefs of physicians about the practice of medicine has been changed overnight by the emergence of clinical practice guidelines. The practices of both professions are determined by myriad intersecting forces that are resistant to sudden change. Charles Darwin's observations about the process of change in natural selection also captures the essence of this process of change in professional practice:

That natural selection generally acts with extreme slowness I fully admit. It can act only when there are places in the natural polity of a district which can be better occupied by the modification of some of its existing inhabitants. The occurrence of such places will often depend on physical changes, which generally take place very slowly, and on

the migration of better adapted forms being prevented. . . . But I do believe that natural selection will generally act very slowly, only at long intervals of time, and only on a few of the inhabitants of the same region. (Darwin 1948 [1859]: 82)

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