Kumho for Clinicians in the Courtroom: Inconsistency in the Trial Courts

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Report Calls for Sweeping Changes At the FDA

By Janice G. Inman

In September, the Institute of Medicine of the National Academy of Sciences, a congressionally created entity dedicated to the study of policy matters pertaining to the public health, issued the results of the study of federal drug safety policy commissioned by the Food and Drug Administration (FDA). The resulting report, titled “The Future of Drug Safety, Promoting and Protecting the Health of the Public” and published in the Archives of Internal Medicine, has been widely anticipated in light of recent publicity surrounding Vioxx® and other drugs that, subsequent to FDA-approval, proved more dangerous than thought. The authors' goals in carrying out the study included gaining a better understanding of the FDA's current role and the roles of other actors in the process and assessing how changes in these organizations and systems could help promote increased drug safety and better public confidence. The committee's bottom line assessment was that major changes in the way the FDA is organized and funded are needed.

SOME ORGANIZATIONAL CHANGES

The Center for Drug Evaluation and Research (CDER) at the FDA weighs the risks and benefits of new drugs, but thorough oversight of approved medications is lacking.

Kumbo for Clinicians in the Courtroom

Inconsistency in the Trial Courts

By Harold J. Bursztajn, Milo Fox Pulde, Darlyn Pirakitikul and Michael Perlin

Two Supreme Court rulings, Daubert v. Merrill Dow Pharmaceuticals Inc., 509 U.S. 579 (1993) and Kumbo Tire v. Carmichael, 526 U.S. 137 (1999), have had a profound effect on the treatment of expert testimony in the courts. In 1993, the Supreme Court, in Daubert, articulated guidelines for admissibility of scientific expertise as testimony. Later, in 1999, in Kumbo, the Court focused on the admissibility of clinical expertise as testimony.

More recently there has been increasing recognition of the inconsistency of trial courts in their construction and articulation of evidentiary standards to medical testimony. One proposed remedy is that “Physicians should respond by correcting courts' misinterpretations of medical practice and assisting in the development of legal standards that encourage thoughtful and informed consideration of medical testimony by judges and juries.” Kassirer JP, Cecil JS: Inconsistency in Evidentiary Standards for Medical Testimony: Disorder in the Courts. 288 JAMA 1382, Sept. 2002.

However, in actual practice, the integrity of a clinical expert's testimony does not depend on the clinician alone. Rather, both the understanding of the retaining attorney as to what is needed to formulate an objective expert opinion, as well as the clinician's dedication to doing so, are essential. Therefore, it is important to improve communication between testifying clinical experts and the attorneys who retained them in the service of providing the finders-of-fact with the most valid and reliable clinical expertise.

DAUBERT AND KUMBO: WHAT THE CASES HELD

In 1993, Daubert changed the medico-legal landscape. The ruling, binding on federal courts and also used as a guideline by many state courts, allowed jurors to hear evidence and weigh facts from experts whose testimony included novel scientific theories, if the case warranted — even if those theories had not gained “general acceptance” in the scientific community — as long as the testimony was “relevant” and “reliable.”

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Daubert established that the test for expert testimony admissibility would be whether it followed the rules of the scientific method. Before Daubert, the Frye test, enunciated in Frye v. U.S., 293 Fed.1013 (D.C. Cir. 1923), had been the norm. Frye allowed judges to exclude evidence from expert witnesses if it had not been “generally accepted.”

In 1975, the Federal Rules of Evidence were enacted. FRE 702 represented a direct challenge to Frye by stating that expert testimony would be admissible as long as it was responsible for determining the facts of a case — usually a jury. The testimony no longer had to meet the “general acceptance” standard. However, defense-oriented critics asserted that Rule 702 allowed experts to present shoddy or “junk science” to juries in support of plaintiff injury claims.

Daubert

Daubert was decided at a time when “novel” no longer meant “suspect,” and the Supreme Court specified in Daubert that the following five factors should be considered in assessing the reliability of scientific testimony: 1) whether the expert’s hypothesis has been tested; 2) whether there has been peer review and publication of the methodology; 3) the frequency of erroneous results; 4) standards controlling the technique’s operations; and 5) acceptance of the methodology in the scientific community.

Under Daubert, judges were assigned a “gatekeeper” role to determine whether the expert’s methodology was sound. In

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civil cases, post-Daubert courts are more likely to exclude challenged expert evidence than they had been before under the Frye standard. Dixon and Gill (2001) found that challenged expert evidence was excluded about 50% of the time pre-Daubert. Saiki M, Faigman D: Expert Evidence After Daubert. 1 Ann Rev Law and Social Science 105, (2005). That figure rose to as much as 70% in years post-Daubert. Dixon L, Gill B: Changes in the Standards for Admitting Expert Evidence in Federal Civil Cases Since the Daubert Decision (2001). Daubert’s requirements, when implemented, have thus had profound implications for both medical experts and lawyers.

Though Daubert signaled the intent of the court to establish explicit scientifically based rules of admissibility and hold the testimony of medical experts to a higher standard, the reality of the practical application of these rules suggests that we have not come far from the comments of Judge Hand in 1901: “No one will deny that the law should in some way effectively use expert knowledge wherever it will aid in settling disputes. The only question is as to how it can do so best.” Learned Hand, Historical and Practical Considerations Regarding Expert Testimony. 15 Harv. L. Rev. 40 (1901).

Kumbo

It took the Kumbo ruling to extend Daubert from scientific to clinical expert opinion formulation and testimony: “The objective of the Daubert gatekeeping requirement is to ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, [should employ] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”

Kumbo did more than simply restate the holding of Daubert. It held that the Daubert “gatekeeping” obligation applies to both testimony based on “scientific” knowledge, as well as that based on “technical” and “other specialized” knowledge. In making the gatekeeping determination, the trial court “may” consider one or more of the five specific Daubert factors if it will help ascertain continued on page 4
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da thing income which is not so in fact." Burk-Waggoner Oil Association v. Hopkins, 269 U.S. 110, 114 (1925). If the amount received by Murphy was for something that is normally not taxed, it could not fit within the definition of income under the Sixteenth Amendment.

The amounts paid to Murphy were not on account of lost wages or taxable earnings. To the contrary, the court found that they were paid to her to make her "emotionally and reputationally whole." The amounts paid were intended to return her reputation to the state that existed prior to the harm which she suffered. There was no addition to or accession to wealth but rather a restoration. If what Murphy received was not income, taxing the damage award for something that is normally not income, regardless of the presence or absence of physical manifestation. As such, any legislation which draws into the ambit of income items those things the framers of the Sixteenth Amendment understood to be nontaxable is by definition unconstitutional.

What Murphy Means to Your Clients

If the Murphy opinion stands, it promises to affect cases that have been settled, gone to verdict, are presently in the courts or are merely disputes in gestation. For those cases that have not been resolved yet, the cost of resolution may well have gone down. Excluding recoveries for personal injuries without physical manifestation — for emotional distress, damage to reputation, or psychological harm, to name a few — from the definition of income under Code Section 61 means that plaintiffs now have nearly 40% more of their recoveries available to them without diminution by taxes.

For those cases already resolved, whether by verdict or settlement, plaintiffs have filed income tax returns reporting their awards and recoveries as taxable income. For those settlements involving the 2003 taxable year and thereafter, plaintiffs should now consider filing claims for refund. Outside of the Fifth Circuit these claims will invariably be denied. Plaintiffs across the country would then be able to bring their own refund suits citing Murphy as authority for recovery of taxes paid on awards for nonphysical harms suffered from tort like acts.

The IRS is carefully considering its next move. The Murphy decision was penned by the Circuit's Chief Judge and was unanimous, suggesting that en banc review might very well come out the same way. It is possible that the IRS might petition for certiorari given that a lower court struck down federal legislation on constitutional grounds. Other taxpayers around the country might file their claims for refund and, when denied, take their claims to their respective Circuit Courts of Appeal, potentially creating a conflict among the Circuits, again enticing the Supreme Court to act, albeit on a delayed basis. No matter what happens next, we have this surprising decision from what was thought to be a routine matter. Clients and counsel alike should begin to take steps necessary to capitalize on this opportunity. Details on the final chapter are sure to follow.

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whether the testimony is "reliable." Overall, Kumho found that the test for reliability is flexible and that "Daubert's list of specific factors neither necessarily nor exclusively applies to all experts in every case ... Rather the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect of its ultimate reliability determination."

Commentary on Kumho has been mixed. While some have applauded Kumho for admitting certain expert evidence rather than simply banishing it as non-science; others have also raised concerns about the role of judges, and how Kumho may in effect be replacing the word of experts with the word of judges. "Together, Daubert

Kumho for admitting certain expert evidence rather than simply banishing it as non-science; others have also raised concerns about the role of judges, and how Kumho may in effect be replacing the word of experts with the word of judges. "Together, Daubert
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and Kumbo Tire do a remarkably clear job of commanding judges to properly scrutinize fields, presumably including the forensic identification sciences, before admitting opinions from those fields' practitioners. But one can never underestimate the ingenuity of judges in finding ways to evade rules that tell them to do something that would lead to a result contrary to the one suggested by their intuitions. Saks MJ: Banishing Ipse Dixit: The Impact of Kumbo Tire on Forensic Identification Science. 57 Wash. & Lee L. Rev. 880, 880 (2000).

Others have been less receptive to Kumbo. One observer, by way of example, saw Kumbo as an effective undoing of Daubert: “The Daubert factors may or may not be relevant to the reliability of the proffered expert testimony. The problem, though, is that Kumbo leaves judges with almost no guidance about how to determine whether such testimony is reliable.” Haack S: Defending Science Within Reason. 254 (2003). However, it should be noted that Kumbo does emphasize the need for corrigibility——or correctibility——rather than a simple “it is because I say so.”

In its emphasis on making transparent and thus corrigible the process by which existing data is connected to offered opinion, Kumbo is well in tune with current clinical practice standards. Medical experts now practice in a climate in which the previously private world of doctor and patient has come alive with the sounds of doctors justifying their decisions to a variety of third parties as well as with increasingly informed and mistrustful patients. The Internet information explosion, reduction of time with patients and the need to justify decision-making to nonclinical third parties have placed greater emphasis on patient education and the corrigibility of clinician reasoning. However, it is important to note that, while physicians should make use of the current best available external evidence about medical care (as the practice of evidence based medicine calls for), such physicians also need to be wary of turning this practice into a substitute for actually assessing the primary literature and understanding its validity. Physicians need to be able to change their minds, to update, revise, and discover and then justify their opinions as new reasons are offered, data introduced and analyses completed. In effect, clinicians now often practice in a consultative mode where transparency of clinical judgment and accountability under conditions of clinical uncertainty are the rule. Without this transparency, mistrust and suspicion would pervade the doctor-patient relationship, for what is not transparent is too often assumed to be biased or corrupt. Thus, it is important for physicians to be able to articulate the basis of their clinical reasoning to patients, colleagues, and third parties. No longer can clinicians simply be silent, or when a clinical opinion is challenged, simply respond with an “it is because I say so” paternalism.

GUIDELINES FOR CLINICIANS

What then can a medical professional and the retaining attorney do to make sure that expert testimony will be considered admissible by the trial judge? There is no question that the cases we’ve discussed may confuse clinicians. In an effort to ameliorate some of this potential confusion, we suggest the following guidelines be used in cases that raise Daubert/Kumbo issues:

Integrity

It is imperative that experts follow the highest standards of their profession while preparing to testify and when testifying. Experts must be objective, independent, and preserve their integrity in an adversarial process. They must avoid conflicts of interest and testify accurately and appropriately. This is critical if expert testimony is to be regarded as reliable.

Competence

If Daubert/Kumbo demands that the expert’s testimony represent both the clinical evidence and medical facts, then the expert must have credible experience in the practice of medicine, knowledge and familiarity with the legal process and standards, and the ability to offer a valid translation of clinical decision-making fundamentals into a meaningful forensic opinion. An active clinical and consulting practice, teaching experience and an in-depth understanding of the relevant facts, analyses, methods and controversies is important. Being able to update the nature and degree of certainty of one’s clinical formulation is also a critical attribute for the expert who successfully fulfills the post-Daubert/Kumbo standards.

Clinical Reasoning

The practice of evidence-based medicine and thrust of Daubert are the same — the methods used to reach a conclusion must be scientifically accurate, valid and applicable to the case at hand. Experts and their retaining attorneys need to realize that the new federal and state court mandates demand their opinions have strong foundation, and may only be admissible if the opinions follow the methodological rules of clinical decision-making under conditions of uncertainty, and are reliable and relevant. Experts need to understand the principles of clinical evidence and clinical reasoning, apply them to each case and incorporate them in their opinion formulation. For example, substitute the word “case” for “patient” or “patient’s illness” and the practice recommendation quoted here sounds remarkably like the Daubert court’s recommendations for expert testimony and can be applied in other situations: “Does this diagnostic hypothesis adequately explain all the patient’s clinical findings? Is this hypothesis pathophysiologically coherent? Does this diagnostic hypothesis provide the best fit to the pattern of the patient’s illness? Is there no hypothesis that is simpler? Is this diagnostic hypothesis robust to attempts to falsify it? Does this diagnostic hypothesis best predict the subsequent course of the patient’s illness?” Kassirer JP, Kopelman RI: Learning Clinical Reasoning. 32 (1991).

Communication

Expert witnesses must understand that they function as teachers and educators, and the effective performance of their role demands a unique combination of oral and written communication skills and the ability to relate to many different audiences. The expert needs to maintain objectivity, yet must also maintain ongoing dialogue with

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the retaining attorney and experts from other disciplines so as not to “lose sight of the forest for the trees.” Experts must be able to articulate a clear, concise, coherent, and compelling narrative with respect, authenticity and sincerity to the triers of fact of the case. This means paying attention to both the stated content of the testimony and the manner in which it is offered. Content is most effectively communicated through an in-depth knowledge. The expert must conduct a thorough review and analysis of the data and be familiar with the totality of the facts, conflict as to facts, and the literature, and be meticulous in detail, organization, and reasoning. Effective experts understand that testimony is an ongoing educational workshop with the judge and the jury. Experts who communicate and collaborate with attorneys can ensure that on direct questioning the attorney asks the fundamental questions that permit them to simply yet deeply present their analyses. Furthermore, the expert must be able to carefully analyze and anticipate how any direct examination testimony can be distorted on cross. In a consultative role experts can also provide insights that enable the attorney to more effectively cross-examine opposing witnesses.

Respect the Intangible

...Yet make it tangible. As when consulting to a fellow clinician, experts have to pass the “dinner companion” test or the truth of their opinions will not resonate with the jury or influence the outcome. In other words, the expert must be able to make clear to the layman that his testimony is reliable and can be trusted. On one hand, testifying experts need to exhibit sufficient commitment to their opinions to meet the level of medical or clinical certainty expected from one clinician consulting to another. On the other hand, clinical commitment and medical certainty are not satisfied by unsupported statements from the expert. The validity, reliability and relevance of the expert’s method need to be illustrated in a meaningful manner. The expert’s report is the most tangible evidence of the expert’s methods.

Heuristics

“Heuristics” is a cognitive psychology construct that refers to the implicit rules of thumb of reasoning that individuals use to oversimplify complex information-processing tasks. On one hand, the use of these heuristic devices may be helpful in making complex decisions in real time. Garb H: Clinical Judgment and Decision Making. 1 Amn. Rev. Clin. Psychol 67 (Apr. 2005). However, used out of context, heuristics can cause decision-makers to ignore or misuse items of rationally useful information, leading to distorted and systematically erroneous decisions. For example, as a result of the over-reliance on the “vividness” heuristic, one single, vivid, memorable case can swamp a mountain of abstract, colorless, yet relevant data. Heuristics also have implications for the different ways in which judges and juries approach the decision-making process, particularly given the fact that judges are more likely to follow precedent while juries are more likely to follow group decision-making patterns. A major pitfall in group decision-making is the vulnerability to a risky shift to vivid examples. If ordinary people’s judgments are distorted by cognitive biases, then experts prepared with staggering statistics or other striking examples have the capacity to take advantage of the vividness heuristic and influence the jurors’ decisions. Judges are also vulnerable to the use of heuristics. In particular, an individual judge may be especially susceptible to the “anchoring and adjustment” and conservatism heuristics. The “anchoring and adjustment” heuristic is characterized by the decision-maker coming to a provisional judgment on the basis of the testimony heard first, and then adjusting his or her opinion on the basis of later testimony. The result is that the earlier testimony remains dominant and pervades the decision-maker’s entire decision-making process. Related to the anchoring heuristic is the conservatism heuristic. In anchoring, a decision-maker is influenced by earlier examples, and anchoring does not typically occur when the interval between these examples is long and filled with other judgments or items. In conservatism, on the other hand, the decision maker will continually be influenced by an opinion he believes he held earlier, even though he may or may not have. In many areas of the law, research reveals that the use of such heuristic devices “permeates both the trial and the appellate processes.” Perlin ML: Pretexts and Mental Disability Law: The Case of Competency. 47 Univ. of Miami L. Rev. 625, 659 (2003).

It is essential that expert witnesses insulate themselves from the “pernicious” use of such heuristics in their testimony. Perlin ML: There’s No Success Like Failure and Failure’s No Success At All: Exposing the Pretextuality of Kansas v. Hendricks. 92 Northwestern Univ. L. Rev. 1247 (1998). Being cognizant of the presence of heuristic devices, and how they are used can be extremely important in challenging the methodology of opinion formulation of a clinician expert.

While these guidelines are imperfect at best, they are aimed at mitigating some of the confusion faced by clinicians retained as experts in the post-Kumbo era. The clinical expert faces many challenges, and must balance the need to demonstrate their validity as scientists with the need to be able to communicate with laypersons in a cogent manner. These guidelines serve as an attempt to help in this endeavor.

Post-Kumbo Justice

Kumbo has had a tremendous impact on the role of the testifying clinical expert in helping the finder of fact’s pursuit of justice. In the post-Daubert/Kumbo world, there are more incentives to identify and use qualified clinical experts and to collaborate with them; Daubert/Kumbo challenges to exclude or limit expert testimony, the increased complexity of clinical decision-making and information and the growing sophistication of judges and jurors secondary to the dissemination of knowledge by the media and Internet, all contribute

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to the need for guidelines distinguishing between acceptable and unacceptable expert evidence.

Although alternatives to the current system have been suggested, few seem feasible to apply. It has been recommended that, in complex cases, judges use their own "experts" or expert panels to assist in deliberations. Walker L, Monahan J: Scientific Authority: The Breast Implant Litigation and Beyond. 86 Virginia L. Rev. 801 (2000). There is no guarantee, however, that court-appointed experts will be free from bias. Although the challenges for the judicial system in evaluating complex technical and scientific issues are formidable, court-appointed experts "pose risks, due primarily to outdated confidence in the certainty of science and assumption about the neutrality of experts who are free of party allegiances," Deason RE: Court-Appointed Expert Witnesses: Scientific Positivism Meets Bias and Deterrence. 77 Oregon L. Rev. 59 (1998). Critics have pointed out that the use of designated panels of experts or specialized courts undermines the "checking function of the adversary system." Moreover court appointment tends to confer upon court-appointed experts, some of whom may have subtle yet substantial conflicts of interest that even they themselves may not be aware of, the halo of judicial infallibility. By the same token, the blind use of clinical guidelines as a gold standard has to be avoided in light of the emerging data as to conflicts of interest due to potential vested interests of guideline authors or their being funded by third parties (managed care organizations, pharmaceutical companies) which may have a stake in the process and content of formulation of such guidelines. Taylor R, Giles, J: Cash Interests Taint Drug Advice. 437 Nature 1070 (2005).

Experiments have been performed to ascertain the conditions under which judges accept expert advice. In a study by Swol and Sniezek (Van Swol LM, Sniezek JA: Factors Affecting the Acceptance of Expert Advice. 44 Br J Soc Psychol 443 (Sept. 2005)), two experiments were performed to determine factors that could increase the utilization of expert advice. In the first experiment, five factors were examined: 1) the judge's trust in the adviser; 2) adviser confidence; 3) adviser accuracy; 4) the judge's prior relationship with the adviser; and 5) the judge's power to set payment to the adviser. In the second experiment, trust was examined without the role assignment to judge or adviser. The study found that expressions of high confidence by the advisers increase the acceptance of advice, and that even when participants communicated freely, face-to-face, written expressions of confidence were the best predictors of advice acceptance.

As for evidence, it is also worth noting that there has been a split in the federal appellate circuits in the construction of Daubert in subsequent cases. For example, regarding social framework evidence, while the Third Circuit in *Heller v. Shaw Indus.*, 167 F. 3d 146 (3d Cir. 1999) adopted a relatively open approach and has allowed a good deal of clinical judgment to support the opinion, the Fifth Circuit in *Black v. Food Lion Inc.*, 171 F.3d 308 (5th Cir. 1999) took a more strict approach, and only allows opinion on medical causation that is supported by considerable research.

While Daubert has had a profound effect on clinical experts and lawyers, some plaintiffs' attorneys and their advocates have claimed Daubert to be unnecessarily burdensome, and have even gone as far as to say that Daubert has had a substantial negative effect on the plaintiff, noting that it adds substantially to the quantum of evidence that a plaintiff must introduce, and to the power of the judge to affect the outcome of the trial. Lakoff G: A Cognitive Scientist Looks at Daubert. 95 Am J Public Health 114 (2005). On the other hand some defense-oriented commentators decried the persistence of Frye in a variety of state courts. Bernstein D: Quackspertise. The Wall Street Journal, Sept. 30, 2006, at A9.

**CONCLUSIONS**

Variability of rule and interpretation aside, attorneys and judges who possess some of the same attributes that are indicative of clinical expertise are also in the best position to do justice. These include being open to learning new facts, making well founded inferences, and a renewed commitment to open and candid communication and collaboration.

As the complexity of cases increases it is even more critical that attorneys provide the clinical expert with a complete database of discoverable information with a realistic timetable so the expert can review and analyze both the medical facts and relevant literature in order to develop an opinion that is transparent and corrigible. Clinical experts need to be prepared to engage in a transparent and corrigible opinion formulation process focused on achieving the requisite degree of medical or clinical certainty (most often, more likely than not) rather than to simply offer opinions. Attorneys must eschew clinical experts whose testimonies are based on such opinions. Clinical experts also need to anticipate how their testimony can be distorted on cross-examination and be prepared to address such distortions. In this new post-Daubert/Kumho environment attorneys and judges will find most helpful those experts who are able to articulate not merely their opinion but the process by which they employed their expertise in data review and analysis and methods of inference to formulate their opinion to the requisite degree of professional certainty required by the finder of fact.

By making clear in a report the reasoning and analysis which is at the heart of an opinion formulation, the twin goals of allowing for earlier dispute resolution and for preparation of testimony which can withstand Daubert- or Frye-based challenges if the case goes to trial can each be achieved.