Commentary: *Helling v. Carey*, *Caveat Medicus*

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Forensic experts should be aware of the increasing importance of clinical practice guidelines (CPGs) in various legal settings. CPGs are a type of learned treatise and are accepted into court proceedings under hearsay exception provisions. The courts now use CPGs as shorthand for the standard of care in making malpractice determinations. However, medical guidelines can function as a sword or a shield in the courtroom arena. The *Helling v. Carey* medical malpractice case serves as a frightful reminder of the potential consequences of allowing courts to craft their own standards of medical care.

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A clinical practice guideline (CPG) is a statement that seeks to guide medical decision-making and provides clinicians with direction for diagnosis, management, and treatment in specific areas of health care. Such medical algorithms have been in use in the United States for approximately 50 years.[1] In contrast to previous approaches, which were often based on tradition or authority, CPGs are a synthesis of the current clinical and empirical evidence within the overarching paradigm of evidence-based medicine. Although they usually include summarized consensus statements, they also cover practical matters that arise in day-to-day clinical care. CPGs are produced by private entities (insurance companies, HMOs, and PPOs) and at national or international levels by medical associations or governmental bodies, such as the U.S. Agency for Healthcare Research and Quality (AHRQ).

Additional objectives of CPGs are to standardize medical care, to raise the quality of care, to reduce risk (to the patient, the health care provider, medical insurers, and health plans) and to achieve an optimal balance between cost and other medical parameters such as clinical effectiveness, specificity, sensitivity, and the like. Although CPGs are regarded by most physicians as helpful in guiding and informing clinical practice, their implementation as documents of standard of care continues to be resisted by many physicians.[2]

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Learned Treatises

The introduction of medical knowledge into legal proceedings has long been a contentious process. The law seeks certainty, but the nature of scientific knowledge is, and always has been, contingent, in that knowledge is always incomplete. Since the process occurs in the courtroom, not the laboratory, attempts to conform medical information to legal dictates have proven difficult.

In her article, "Clinical Practice Guidelines As Learned Treatises: Understanding Their Use As Evidence In the Courtroom,"[3] Patricia Recupero provides a comprehensive and thorough discussion of CPGs and the ways in which they are applicable to the court setting. CPGs are regularly introduced into legal proceedings as a learned-treatise exception to the hearsay rule (as applied to scientific knowledge). Recupero compares the two primary approaches to the introduction of scientific learned treatises: the conservative method laid down in *Frye v. United States* [4] and the liberal approach enumerated in the Federal Rules of Evidence of 1975.[5] The discussion ends with an examination of the *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[6] revolution (although *Daubert*'s liberal evidentiary approach to scientific knowledge appears to have resulted in seemingly unintended effects[7]).

In *Daubert*, the U.S. Supreme Court sought to clarify the intent of the Federal Rules of Evidence

vis-à-vis the admission of scientific evidence into legal proceedings. In so doing, the Supreme Court held that federal trial judges are the gatekeepers of scientific evidence. Under the *Daubert* standard, therefore, trial judges must evaluate proffered expert witnesses to determine whether their testimony is both relevant and reliable, a two-pronged test of admissibility. As to reliability, the Court intended to equip judges with guidelines by which they could better vet the authoritativeness of scientific evidence. In so doing, it sought a happy medium between the exclusivity of the general-acceptance approach of *Frye* and the unrestricted approach favored by some legal theorists (although many feared that judicial openness would lead to a further proliferation of junk science in the courtroom[8]).

One problem that arises in the evaluation of scientific evidence is how courts handle learned treatises. Unlike other forms of authoritative reference, these documents are written by someone who is usually not in the courtroom or available during legal proceedings. Authors of scientific treatises are therefore not sworn and are unavailable for cross-examination. This problem is addressed by the Federal Rules of Evidence in Rule 803(18),[9] which allows the admission of learned treatises such as textbooks, journals, and medical guidelines, or CPGs, as testimonial evidence. As testimonial evidence, information or direct passages may be read into the official court record by an expert witness, but the treatise itself is not accepted as stand-alone evidence or admitted as an exhibit.

CPGs as Standard of Care

In her article, Recupero details the history of the introduction of CPGs into the legal arena.[3] A primary area in which CPGs have played a large role is in medical malpractice cases, in part because medical malpractice cases, by their very nature, focus on standard of care. In each malpractice case, the physician's care is evaluated by the metric of the applicable standard of care. In the past, the so-called locality rule meant that physicians would be adjudicated according to the prevailing local standard of care. Over time, the evident variability of care between different localities (e.g., rural versus urban) led to a move among legal scholars toward a national standard of care. CPGs provide a standard of care based on an evidence-based consensus in a particular area of medicine. This evidence-based approach to arguments concerning standard of care allows attorneys to litigate their cases according to a standardized measure, instead of disparate, traditional, or local standards.

Certainly, the journey toward a national standard of care has not been seamless. In *Helling v. Carey*,[10] the Supreme Court of the State of Washington overturned both lower court and appellate court rulings to find for the plaintiff in a malpractice case. The two defendants, who were ophthalmologists, had correctly followed the standard of care (both the customary local practice and the national standard at the time[11]) by not performing a tonometry test on a patient under the age of 40. Only one in 25,000 persons under the age of 40 is found to have glaucoma. Tonometry tests on persons under 40 result in a high rate of false-positive results.[12] The plaintiff in the case, Helling, had experienced episodes of pain in her eyes for nine years and eventually had significant loss of vision. Finally, when Helling was 32 years old, the physicians in the case administered a tonometry test, and glaucoma was diagnosed. The Washington Supreme Court conceded that the physicians had followed the local standard of care, but found them liable, nonetheless, based on a cost analysis of tonometry. By ruling as it did, the court lurched toward a strict liability standard.[13] Subsequent research has consistently demonstrated that although ophthalmologists nationwide have changed their practice patterns in response to *Helling*, the result has been an increase in the cost of care without a commensurate reduction in morbidity.[11,14]

In *Helling v. Carey*, the court did not enlist expert witnesses to assist in the formulation of the cost analysis argument. *Helling* has not become a precedent followed by other states. Indeed, even in the state of Washington, *Helling* is considered an exceptional circumstance,[15] and the Washington state legislature later enacted a statute intended to overturn *Helling*. But the case serves as a cautionary tale of what can happen when legal professionals choose to navigate the shoals of science alone. Accordingly, as CPGs are implemented into legal proceedings as documents of standard of care, it is imperative that the appropriate medical expert witnesses be consulted to ensure that the adoption of CPGs are consistent with sound scientific and medical principles, as well as accepted ethics practice.

Recupero[3] discusses several medical malpractice cases in which CPGs were accepted by the courts as metrics of standard of care. In a case heard by the

Tennessee Court of Appeals,[16] CPGs were admitted after surviving a hearsay challenge. In *Moore v. Baker*,[17] CPGs were employed to exclude fringe therapies as a basis for a malpractice suit. In *Washington v. Washington Hospital Center*,[18] two conflicting sets of medical guidelines were reviewed in a malpractice case. The District of Columbia Court of Appeals held that both documents could be helpful to a jury in determining the relevant standard of care. In light of *Washington*, Recupero suggests that an "expert may be called upon to testify that a reasonably prudent practitioner may be expected to follow the most current innovations in care even if not yet adopted comprehensively" (Ref. 3, p 294). Such a predicament resonates as too much *Daubert*, not enough *Frye*.

Shield or Sword?

For practicing physicians and expert witnesses called on to provide medically relevant testimony, the manner in which CPGs are employed in the courtroom is particularly important. Will they serve as shields against liability or as swords used to secure malpractice claims? Recupero cites an article published in the *Annals of Internal Medicine*,[19] which indicates that in cases actually filed in court "attorneys used CPGs more frequently for inculpatory than exculpatory purposes" (Ref. 3, p 296). Although physician adherence to CPGs has been used as a shield in medical malpractice cases, the converse has also been true. Maine (among other states) has created medical practice guidelines which, if adhered to by physicians, could be used as an affirmative defense in malpractice cases.[1] Recupero details a Mississippi Court of Appeals case[20] in which departure from the CPG was deemed medically necessary. The plaintiff in this case developed a decubitus ulcer and asserted that he had not been turned every two hours (in keeping with hospital policy and national guidelines). The hospital had departed from the policy because turning the patient caused airway obstruction and consequent drops in oxygen saturation. However, when practitioners depart from CPGs and there is a negative outcome, the deviation may bolster the case for the opposing side. This problem is of particular concern in those cases in which CPGs with conflicting recommendations are introduced into the same malpractice case. As has been previously discussed, courts have typically tended to permit the juxtaposition of conflicting CPGs, allowing the jury to determine which evidence is most compelling.

The jury as arbiter of scientific evidence may raise a plethora of valid concerns. Ultimately, however, experts are not permitted to usurp the role of the trier of fact. Juries have long had to mull over the conflicting opinions of expert witnesses in reaching their findings. They are also frequently called on to integrate disparate pieces of information and make difficult decisions in the courtroom every day. Cases in which conflicting CPGs are presented may pose somewhat of a conundrum for jurists and for the court. This problem notwithstanding, juries operate in an historically adversarial system where conflicting perspectives form the backdrop of legal proceedings. Therefore, the use of conflicting CPGs may be considered simply business as usual in cases that are germane to health care and clinical practice.

Conclusions

Recupero should be lauded for calling attention to the expanding role of CPGs in medicolegal settings. Although physicians value autonomy and reliance on clinical experience, medical practice guidelines serve to standardize care in a way that helps to shield clinicians from legal action. Some physicians who treat patients in the context of a legal setting may fear that CPGs will eventually displace the expert witness as the primary source of medical information for the court. However, such an occurrence seems unlikely, since the law favors a "testimonial" model (as evidenced by the restrictions placed on written scientific information by the Federal Rules of Evidence) and invests "customary practice" as a bulwark against atypical or bizarre modes of care.[21] For those who chafe against CPGs as a stricture on physician autonomy, remember that CPGs may also serve as a bomb shelter in a malpractice determination. In *Helling,* the appellate court threw out the accepted standard of care in favor of its own determination. If *Helling* is the Frankenstein of legal construction, then the CPG is the Easter Bunny. At any rate, better a CPG than no standard at all.

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