Clinical Practice Guidelines as Learned Treatises: Understanding Their Use as Evidence in the Courtroom

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It is important for forensic experts to understand how clinical practice guidelines may enter the courtroom, what role they may play in a trial, and how they relate to expert testimony. Guidelines enter the record in several different ways and in several types of cases, typically with the assistance of an expert witness. A common vehicle for their introduction is the learned-treatise exception to the hearsay rule. Case law before and after *Daubert v. Merrell Dow Pharmaceuticals, Inc.* helps to elucidate the scrutiny that courts may direct toward medical texts proffered as evidence. This article discusses the implications of different rules and relevant case law for the forensic psychiatrist. The discussion notes important considerations for the expert witness, such as how guidelines may affect the expert's role, concerns about the reliability and relevance of scientific evidence, and questions about whether guidelines will be used for inculpatory or exculpatory purposes in medical malpractice trials.

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In recent years, clinical practice guidelines (CPGs) have played an increasingly larger role in shaping both the legal standard of care and the evolving quality of care in modern medicine.[1] As Simon notes, "The standard of care should be distinguished from the quality of care. The standard of care is a legal concept, normatively defined, that is applied to the specific fact pattern of a case in litigation" (Ref. 2, p 99). In the courtroom, CPGs may be considered medical learned treatises. As such, they may be introduced into evidence and may help courts to determine the standard of care or to resolve other important questions in a case. The goal of this article is to help the forensic expert to understand how CPGs function as evidence in a trial and how they relate to the role of the expert witness.

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Clinical Practice Guidelines

CPGs are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Ref. 3, p 39). They may also be termed practice parameters, algorithms, or clinical pathways.[4] Since the growth of outcomes research in the 1970s, the production of CPGs has grown considerably, spurred by the push toward simultaneous quality-improvement and cost-containment measures.[5,6] Congress' creation in 1989 of the Agency for Health Care Policy and Research (AHCPR; now, the Agency for Health Care Research and Quality [AHRQ]) was intended to improve health care, in part by encouraging the development of effective practice guidelines. Thousands of CPGs are now available through an internet database maintained by the National Guideline Clearinghouse (http://www.guideline.gov/), a division of the AHRQ.[7] Other sources on the World-Wide Web include the Cochrane Collaboration (http://www.cochrane.org/) and, in psychiatry, the Texas Medication Algorithm Project (TMAP; http://www.dshs.state.tx.us/mhprograms/TMAP.shtm).

Some states (notably, Maine,[8] but also Florida,[9] Kentucky,[10] Maryland, Minnesota, and Vermont[11]) have attempted to use CPGs in tort reform and health care quality improvement efforts by introducing legislation that specifies how CPGs may apply in alleged malpractice or by authorizing the development of CPGs formally recognized by regulatory bodies. Other states (such as Rhode Island)[12] have been reluctant to adopt statutory measures similar to Maine's. Courts have voiced concern over the implications of such provisions for litigants' constitutional rights, such as due process, the right to a jury trial, and the equal protection clause.[13] Investigative reports by the General Accounting Office[14] and the Office of Technology Assessment[15,16] did not find sufficient evidence to encourage the continued development of such programs on the federal level.

The scope and purpose of CPGs is the subject of some debate. The American Psychiatric Association (APA) explains in a Statement of Intent for its CPGs in 2007 that:

> The APA Practice Guidelines are not intended to be construed or to serve as a standard of medical care . . . . The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the psychiatrist in light of the clinical data presented by the patient and the diagnostic and treatment options available [Ref. 17, p 5].

Similarly, the "Statement of Intent" in the American Academy of Psychiatry and the Law's (AAPL's) Practice Guideline for Forensic Psychiatric Evaluation of Defendants Raising the Insanity Defense states: "These parameters are not intended to represent all acceptable, current, or future methods of evaluating defendants for and drawing conclusions about the insanity defense" (Ref. 18, p S3). Intent and disclaimers notwithstanding, CPGs may have vast implications for patients as well as physicians, and the continued development and spread of CPGs can play a substantial role in shaping the practice of medicine. Furthermore, as one scholar notes, ". . . it is easy to envision [CPGs] assuming a more prominent role in fixing the legal standard for measuring the adequacy of care" (Ref. 19, p 333).

Learned Treatises

To understand how CPGs and other medical learned treatises are used in the courtroom, a brief legal history may be informative. In 1923, the Court of Appeals for the District of Columbia published an opinion in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923),[20] establishing that in order for novel scientific evidence to be admissible, it must have attained the level of "general acceptance" among the relevant scientific community. Over time, the vague definition of "general acceptance" allowed for wide variation in the test's application in different courts.[21] In 1949, the Supreme Court held in *Reilly v. Pinkus*[22] that a medical treatise could be used to cross-examine or impeach an expert witness even when the witness has not acknowledged that the text is authoritative. The Supreme Court of Illinois published two important holdings in the widely cited 1965 case, *Darling v. Charleston Community Memorial Hospital*.[23] The court held that: (1) it is permissible to cross-examine expert witnesses regarding the views of recognized authorities in their field, even if those views are not the basis for the experts' testimony; and (2) accreditation standards are admissible as evidence regarding a hospital's duty toward its patients. The decision broadened the ways in which scientific testimony could be evaluated for reliability, as the court explained: "An individual becomes an expert by studying and absorbing a body of knowledge. To prevent cross-examination upon the relevant body of knowledge serves only to protect the ignorant or unscrupulous expert witness" (Ref. 23, p 259).

Historically, a common practice has been to allow the use of medical or scientific documents (i.e., learned treatises) only for the limited purpose of impeaching an expert witness. By this strategy, an attorney would attempt to undermine an expert's testimony by cross-examining the expert from a text that the witness had deemed authoritative. A conflict between an expert's opinion and information in the text would raise a question of credibility, and the expert's opinion could be impeached. Attorneys familiar with this practice would typically coach their expert witnesses to refuse to acknowledge any proffered text as authoritative. As long as the experts refused to admit that any text was authoritative, the text could not be introduced as a learned treatise, and the witness's testimony would stand.

In 1975, the Federal Rules of Evidence were adopted and subsequently embraced by many state courts. These rules made it easier to enter the contents of a learned treatise into evidence and to use them during a trial, not only for the impeachment of expert witnesses, but also for direct substantive evidence. In federal and state courts adopting the Federal Rules of Evidence, expert witnesses may be permitted to testify from CPGs regarding the standard

of care by reading text from the guidelines into the record. Medical learned treatises would ordinarily be inadmissible under the hearsay rule, because the persons or panels who published them are unavailable for cross-examination or sworn testimony. However, Rule 803 provides numerous exceptions to the hearsay rule. One of these, Rule 803(18),[24] allows for the introduction of learned treatises that have been qualified as reliable authorities by an expert witness or through judicial notice. The use of medical learned treatises in malpractice or similar cases is justified, in part because "reliance on hearsay information certainly is a matter of necessity for physicians . . .[who] regularly rely on medical records, reports, x-rays, and patient information when making a diagnosis" (Ref. 25, p 196). Rule 803(18) limits the use of learned treatises; it allows only the reading of passages and does not permit the jury to receive the treatise as an exhibit in written form. Case law has confirmed this restriction.[26] This provision is designed to keep the evidence "testimonial" (oral) and to prevent the jury from overvaluing the treatise or from conducting its own fishing expedition through the entire work.

In 1993, the United States Supreme Court, faced with the question of what constitutes scientific knowledge under Federal Rule of Evidence 702, rejected the *Frye* "general acceptance" test in favor of an analysis based on the Federal Rules of Evidence[21] in its holding in *Daubert v. Merrell Dow Pharmaceuticals, Inc*.[27] *Daubert* sets forth a standard for courts to address when considering scientific expert testimony and affords courts a means of testing scientific expert testimony for relevance and reliability.[28] In many cases, CPGs may bolster an expert's testimony or credibility to satisfy or survive a *Daubert* challenge. However, in courts applying the *Daubert* standard, a CPG itself must meet the standard before it may be admitted as evidence through expert testimony. As one scholar has noted:

> In the post-*Daubert* review of medical literature, the courts question not only an article's reliability, but the expert's use of literature to support his or her opinions. Consequently, medical or scientific literature ought to exhibit evidence of trustworthiness as demonstrated by the author; or it should at least reflect the academic trappings of an authoritative exposition by a leader in a particular field. In courtrooms where *Daubert* controls admissibility, the use of medical literature to form conclusions not drawn in the literature itself violates the dictates of the scientific method [Ref. 29, p 352].

Other commentators have noted that courts, after *Daubert*, have devoted considerable attention to questions of peer review and publication of opinions or assertions contained in expert witness testimony.[30]

In 2000, the Federal Rules of Evidence were revised to support the standards set forth by the Supreme Court in *Daubert*[27] and two later cases, *General Electric Co. v. Joiner*,[31] and *Kumho Tire Co. v. Carmichael*.[32] The new Rule 702[33] requires that expert testimony be based on reliable principles and methods that are applied to the facts of the case.[34] As this article seeks to illustrate, judicial scrutiny of scientific evidence has played a role in how CPGs are used in the courtroom and has influenced decisions of whether to accept or reject expert testimony.

Practice Guidelines in the Courtroom Today

CPGs may enter the courtroom in several types of cases, ranging from medical malpractice and workers' compensation to criminal proceedings,[35] typically functioning as some evidence of the standard of care. In addition, in establishing the basis of an expert's opinion or in cross-examination of the expert, information about how the expert arrived at his or her opinion and whether there is any evidence to support the witness's opinion is expected. Such information helps to fulfill the expert's role as stated in Rule 702[33] or similar state rules. When CPGs support or contradict an expert's position, they may be useful to the court to help place the testimony in context. The forensic expert may also help the court to understand a medical learned treatise and to judge whether the treatise is appropriate evidence of the standard of care in a particular case.

Rules of evidence and procedures for admitting or rejecting evidence are not uniform. "[M]any states recognize a version of the [learned treatise] exception narrower than that set out in Rule 803(18)" (Ref. 36, p 1267). Some courts specify that the witness must have relied on the treatise in formulating his opinion. Of these, some require that such reliance be acknowledged on direct examination, while others allow reliance to emerge during cross. Other courts, while not requiring that the witness rely on the treatise, require that the expert acknowledge the treatise as an "authoritative" work.[37] (For a text to be considered authoritative by an expert witness, the witness, generally, must consider the work to be a source of reliable information among members of his field.) Some courts allow the use of learned treatises on cross-

examination even when the witness has not acknowledged the text as authoritative, but its status as an authority has been established otherwise (e.g., through judicial notice or through another expert's testimony). In *Alton v. Kitt*, the court permitted an expert witness to testify from the *Physicians Desk Reference* (PDR), which the court deemed to have "inherent trustworthiness . . . as a medical text . . ." (Ref. 38, p 425). Arguably, most forensic psychiatrists would testify that the PDR lacks inherent trustworthiness, as the information it contains is the result of negotiations between pharmaceutical companies and the FDA. It may be necessary for the expert to help the court or the jury to understand why he or she believes the treatise is not reliable or relevant. Although it is rare that medical treatises are introduced through judicial notice,[35] some CPGs may be deemed sufficiently trustworthy to be admitted under this rule. The Diagnostic and Statistical Manual of Mental Disorders (ed 4; DSM-IV), for example, may survive an expert's denial that it is authoritative, if the record demonstrates that most psychiatrists rely on the DSM-IV and thereby recognize it as an authoritative text.

The scope of the expert's testimony and the admissibility of a particular CPG may vary depending on the type of case, the forum, the source of the CPG, the degree to which the expert believes the guidelines to be relevant and reliable, and the relevance and reliability of the expert's testimony itself. While a full discussion of the ways in which CPGs may enter the record is beyond the scope of this article, it bears noting that CPGs and other medical texts may be admissible under other hearsay exceptions or other rules of evidence. For example, Federal Rule of Evidence 705 permits expert witnesses to "give reasons" for their opinions. Some courts may allow the expert to offer a learned treatise to explain the reasoning behind an opinion, without needing to consider Rule 803(18).[39] Courts may also prohibit the use of medical treatises that do not meet criteria for judicial notice and that have not been introduced under a learned-treatise rule.[40] When CPGs do enter the record, they frequently serve as some evidence of the relevant standard of care, and they may still be used for impeachment purposes.

CPGs As Evidence of the Standard of Care

In medical malpractice litigation, the standard of care is always at issue; "[i]n theory, the physician who complies with the prevailing custom is absolved of liability" (Ref. 41, p 782). Plaintiffs' attorneys seek to demonstrate that the defendant physician has departed from an acceptable standard of care, and the defense usually counters with evidence that the physician's actions comported with the standard of care. Evidence usually involves testimony from medical expert witnesses and sometimes incorporates written documents to support arguments offered by either side. In conjunction with expert testimony, CPGs may help a court to define the standard of care. Case law helps to illustrate this practice.

The Tennessee Court of Appeals allowed the introduction of CPGs published by the American College of Cardiology and the American Heart Association.[42] The guidelines survived a hearsay objection after several medical expert witnesses testified that the guidelines accurately represent the standard of care for exercise treadmill tests. A concurring judge wrote: "Clinical practice guidelines can materially assist the triers-of-fact in medical malpractice cases. Properly authenticated [CPGs] 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" (Ref. 42, p 16). In *Ward v. United States*,[43] the Sixth Circuit rejected a plaintiff's contention that the court should not have relied on medical articles in determining the standard of care in a surgical malpractice trial. Expert witnesses for the defense had incorporated the articles into their testimony and had qualified the texts as reliable and authoritative evidence of the standard of care for a surgical procedure. The Second Circuit, in *Tart v. McGann*,[44] admitted CPGs published by the American Heart Association, noting that ". . . the Rule [803(18)] explicitly permits the admission of medical literature as substantive evidence 'to the extent called to the attention of an expert witness upon cross-examination or relied upon by him in direct examination . . .' as long as it is established that such literature is authoritative" (Ref. 44, p 78). While normally they cannot be introduced as physical exhibits, the contents of CPGs are often introduced as evidence through an expert witness's testimony.

CPGs and other medical learned treatises may be useful in revealing the experimental or unrecognized nature of alternative or fringe therapies or procedures. In *Moore v. Baker*,[45] a woman who incurred a brain injury from a blood clot following a carotid

endarterectomy sued her physician and the medical center, alleging that she had not given fully informed consent. She based her claim, in part, on the fact that the defendants had not informed her of an alternative treatment, namely, chelation therapy. The Eleventh Circuit, deciding for the defendants and upholding the trial court's decision, noted the ample evidence introduced by the defense, including a document published by the American Medical Association and evidence from other medical authorities, showing that chelation therapy was not recognized or accepted by the mainstream medical community as an alternative to carotid endarterectomy.

CPGs may also help to distinguish between appropriate and inappropriate risk-management practices. In one case, CPGs were used to show that an unusual infection control policy for the dental treatment of a patient with HIV (requiring the patient to go to a hospital, instead of the dentist's office, to have a cavity filled) was excessive and inappropriate and may have amounted to discrimination against the patient.[46] These cases suggest that CPGs may help to clarify the boundaries of mainstream medical practice.

CPGs can also help to define new or emerging standards of care. In *Washington v. Washington Hospital Center*,[47] an expert in a medical malpractice case based testimony in part on the American Association of Anesthesiology's "Standards for Basic Intra-operative Monitoring" and an article from JAMA entitled "Standards for Patient Monitoring During Anesthesia at Harvard Medical School." One "encouraged" the use of carbon dioxide monitors during elective surgery, and the other noted that the use of monitors was "an emerging standard" and was "strongly preferred." While these standards were not requirements, the court noted that "[a] standard of due care. . . necessarily embodies what a *reasonably prudent* hospital would do . . . and hence care and foresight exceeding the minimum required by law or mandatory professional regulation may be necessary to meet that standard" (Ref. 47, p 182; emphasis in the original). The District of Columbia Court of Appeals found that the evidence could have helped a jury to determine the relevant standard of care, against which they could compare the actions of the defendant hospital. In some cases, an expert may be called on to testify that a reasonably prudent practitioner may be expected to follow the most current innovations in care even if not yet adopted comprehensively.

CPGs are especially relevant when they have been formally endorsed by a party to a case. In *Price v. Cleveland Clinic Foundation*,[48] a case involving alleged negligent performance of blood tests for a paternity suit (not a malpractice case), the court held that scientific papers used for training employees are not hearsay when introduced as evidence against an employer. While this was not a Rule 803(18) case, it demonstrates how an entire document could come into evidence in written form under ordinary evidentiary rules. If an employer (e.g., a hospital) uses a CPG to train employees, then that CPG could be admitted as an exhibit in paper form—not just excerpts read from the stand—as evidence of what actually should have transpired. As illustrated by *Darling*[23] and discussed earlier, accreditation standards and other professional guidelines held or endorsed by organizations or businesses may be admissible. In one medical malpractice case, the Supreme Court of Minnesota admitted a hospital accreditation manual published by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), which contained CPGs relevant to the standard of care at the hospital where the defendant physicians practiced, despite the physicians' admission that they were not familiar with the manual.[49] Obviously, when a physician has acknowledged a particular CPG as authoritative or has stated that he follows that CPG, the CPG in question may carry additional weight at trial. In a malpractice action, a defendant physician stated in his deposition that he accepted as authority a particular set of CPGs published by the American College of Surgeons. The court noted that the defendant may have failed to follow one of the procedures required in the guidelines, a question of fact to be resolved at trial.[50]

Reliability, Trustworthiness, and Relevance of Learned-Treatise Evidence

CPGs that would be prejudicial are typically not admissible, even if endorsed by a party to a case.[51] Courts seek to exclude any scientific evidence that may mislead a jury because of bias, lack of scientific value, unreliability, or irrelevance. In *O'Brien v. Angley*,[52] the Supreme Court of Ohio declined to permit the introduction of an editorial published in JAMA stating that "[t]he best medicine often requires that a physician depart from packaged insert recommendations" (Ref. 53, p 273) because the editorial was written with litigation concerns in mind,

making the editorial fall outside the concept of an impartial learned treatise. Similarly, risk management guidelines promulgated by a liability insurance carrier, even if signed by a defendant in a medical malpractice trial, may be inordinately prejudicial to the jury. A Colorado appellate court held that such guidelines did not meet the relevance test for scientific evidence, because they were created "by a private insurance company as part of an insurance contract and did not reflect a generally recognized standard of care within the medical profession" (Ref. 51, p 238). Experts may assist attorneys in sorting out potential sources of bias or prejudice in CPGs to be proffered at trial.

Litigation bias is but one of many factors that can detract from a learned treatise's reliability. Conflicts of interest, sponsorship or funding by parties with an interest in the outcome of a case, or lack of scientific rigor may impair a text's admissibility. In *Meschino v. N. Am. Drager, Inc.*,[54] the First Circuit declined to admit medical articles published in *Health Devices Magazine*, explaining that mere publication of an article does not make one a reliable authority; the court reasoned:

> [W]e would not accept plaintiff's argument that the contents of all issues of a periodical may be qualified wholesale under Rule 803(18) by testimony that the magazine was highly regarded. In these days of quantified research, and pressure to publish, an article does not reach the dignity of a "reliable authority" merely because some editor, even a most reputable one, sees fit to circulate it [Ref. 54, p 434].

In a similar case, the Alabama Supreme Court held that while a medical journal may be a trustworthy treatise, the articles therein are not necessarily trustworthy treatises themselves.[55] Courts may apply similar scrutiny to CPGs, questioning, for example, whether guidelines are informed by empirical research, whether they are subject to peer review, and how often they are reviewed or updated.

The forensic expert's publications, while possibly qualifying him as an expert in the field, may not always be ideal learned treatises as substantive evidence. A witness's assertion that a text he authored is considered authoritative by other physicians may not carry the same credibility as would an impartial endorsement. The Second Circuit upheld a trial court's decision to exclude a medical text authored by the physician who was a defendant in a medical malpractice action. The court reasoned that the book's ". . . admission would remain subject to a balancing of probative value against danger of prejudice . . . a balancing that would favor exclusion because of the danger of prejudice inherent in recognizing a book authored by the defendant in a medical malpractice case as a learned treatise" (Ref. 56, p 991). While treatises authored by expert witnesses arguably should be less prejudicial to a case, much depends on the scientific facts of the case and the particular court's approach toward admitting or excluding scientific evidence. If Dr. Jane Doe has received funding from Acme Pharmaceuticals for a study she conducted and published on Drug X, her experience studying the drug may qualify her as an expert witness for a malpractice case in which Drug X allegedly caused harm to the patient, but a CPG she helped to develop for Acme Pharmaceuticals may not be ideal evidence of the standard of care.

Judicial scrutiny of scientific treatises looks not only to the reliability or objectivity of a text, but also to its relevance to the claim it allegedly supports. In *Ellis v. Int'l. Playtex, Inc.*,[57] the Fourth Circuit, citing *Frye* and Rule 803(18), refused to permit an expert witness to read into evidence a medical article that was insufficiently relevant to the case at hand, because there was no evidence that the plaintiff sustained the type of injuries described in the article. The court opined

> . . . that the potential prejudicial effect of the testimony outweighed its probative value . . . . We do not believe, therefore, that it was unreasonable for the district court to conclude that under these circumstances the article was likely to cause confusion or invite unwarranted speculation by the jury about the facts of this case [Ref. 57, p 306].

The Sixth Circuit rejected testimony by a medical expert for plaintiffs in a toxic tort case, noting that the scientific literature cited in the witness's testimony did not actually support the expert's claim.[58] The court had also considered the fact that the expert coauthored a peer-reviewed paper on the chemical in question when considering the expert's eligibility to testify. In a similar holding, a United States District Court disqualified an expert witness from testifying because the basis of her testimony did not withstand analysis by *Daubert* standards.[59] In its decision, the court focused on the medical expert's use of scientific literature and reasoned that she had inappropriately used a textbook's explanation of acquired or adaptive immunity to support her conclusion that a particular chemical released from a particular product can cause sensitization to that chemical. While citing relevant CPGs may strengthen an expert's testimony when the CPGs support the expert's opinion, stretching

the relevance of a text merely to footnote one's testimony may weaken credibility. Courts may hold expert witnesses to high standards of scientific reasoning, and even reliance on well-respected or authoritative texts may be questioned on the basis of relevance.

Shield or Sword?

Some commentators have expressed concern that the adoption of CPGs, and particularly their use in medical malpractice trials, will spur the growth of "cookbook medicine," undermining physician autonomy or even detracting from the quality of care. Others have speculated that CPGs may be useful as a shield against physician liability.[60] Of importance is that compliance (or lack thereof) with CPGs may influence whether a liability claim leads to the courtroom. In an oft-cited report published in the *Annals of Internal Medicine* in 1995, Hyams and colleagues[61] examined malpractice claims and surveyed attorneys to determine how CPGs figured into malpractice proceedings. Among cases actually filed in court, attorneys used CPGs more frequently for inculpatory than exculpatory purposes. However, attorneys noted that when CPGs seemed to offer exculpatory information (e.g., the defendant physician's compliance with guidelines may have been a defense to liability), they were less inclined to accept the case. The most frequently used CPGs were those promulgated by professional medical societies, hospitals, and JCAHO.[61]

Individual cases vary considerably, and even the most comprehensive and evidence-based CPGs cannot account for the innumerable factors that come into play in certain cases. Contrary to the fear that CPGs in the courtroom will lead to regimented, restricted, and mediocre care, courts have generally upheld sound clinical judgment, not inflexible or potentially outdated guidelines, as the standard of care. Adherence to CPGs of the American College of Obstetricians and Gynecologists was an insufficient defense to malpractice liability where the plaintiff's expert witness testified that the defendant physician departed from the applicable standard of care in delaying a Caesarian section.[62] The court emphasized the importance of the obstetrician's personal training and experience. Adherence to CPGs is no guarantee against liability if sound clinical judgment requires a different course of action.

Conversely, departing from guidelines does not necessarily subject a physician to liability if the departure was medically appropriate. Mirroring the cautionary statements of intent typically found in professional CPGs, one scholar has explained that: "CPGs, by their nature, are generalizations that do not necessarily apply in a given instance" (Ref. 63, p 376). In a recent case, the Mississippi Court of Appeals affirmed a trial court's ruling in favor of a defendant medical center in a malpractice case.[64] The plaintiff, while undergoing treatment for substantial burns and an inhalation injury incurred in an automobile accident, developed a bed sore and sued the hospital for failing to conform to guidelines suggesting that patients be turned once every two hours to prevent the development of such sores. The guidelines that the plaintiff offered in the case were both the hospital's own standards and national guidelines. The court, in rejecting the plaintiff's argument, noted two experts' testimony that the guidelines were merely suggestions, not requirements, and that the patient's condition justified a departure from the guidelines. In this case, turning the patient resulted in an airway obstruction that impaired his oxygen saturation level and thereby threatened his survival; to ensure that he was able to breathe, the hospital staff had to keep the patient supine.

Another concern raised by the use of CPGs as evidence of the standard of care is the fact that different sets of guidelines may contain conflicting recommendations. There may be more than one medically appropriate course of action for a particular patient, but the hindsight bias that may arise in a malpractice trial sometimes obscures this reality. Some courts have addressed this problem directly by allowing the jury to determine which evidence is the most compelling in a case. In *James v. Woolley*,[65] a malpractice action against an obstetrician, the Alabama Supreme Court allowed testimony based on the technical bulletin of the American College of Obstetricians and Gynecologists regarding the appropriate standard of care. While other experts disagreed with the witness who cited the guidelines, the court noted that it was the responsibility of the jury, not the court, to decide which experts were most credible. In a malpractice suit against a physician for failure to diagnose breast cancer, the court allowed evidence based on two conflicting sets of guidelines.[66] The plaintiff introduced evidence that the American Cancer Society recommends yearly mam-

mograms for women aged 50 years and older, and the defendant offered evidence from the American College of Obstetricians and Gynecologists that recommended only "regularly" scheduled mammograms, where "regular" referred to mammograms within the physician's discretion. The Supreme Court of Pennsylvania applied a two-schools-of-thought analysis and allowed the testimony, noting that a sufficient number of physicians subscribe to each set of guidelines for both to be valid evidence.

Compliance rates with CPGs may be low, even though there is evidence to suggest that their implementation results in improvements in the process of care.[67] Scholars have noted a tendency among clinical physicians to resist information and guidelines proffered by research scientists.[4] Some physicians view CPGs as a threat to their freedom to exercise professional judgment and a possible threat to the continued improvement of medical practice.[63,68] Compliance with guidelines, when clinically inappropriate, may worsen risk in some scenarios. However, when a health care provider departs from a CPG, and harm results, the provider's failure to follow a clinically appropriate CPG may become additional evidence that there was a deviation from the applicable standard of care.

Implications for the Expert Witness

Some have speculated that the continued growth of CPGs will reduce, if not eliminate, the need for expert witnesses in medical malpractice cases.[69] To the author, this seems unlikely. Expert witnesses are necessary to help provide context for medical learned treatises and to help courts to understand complex scientific or clinical reasoning. Indeed, in *Dartez v. Fibreboard Corp.*,[70] the Fifth Circuit upheld a defendant's objection to the introduction of medical articles on the grounds that the articles did not meet the limited criteria for evidence specified under the learned-treatise exception to the hearsay rule. The articles had been improperly introduced as exhibits without the assistance of medical testimony to qualify their implications to the jury. Furthermore, this article's earlier discussion of the impact of bias or irrelevance on courts' decisions to admit or exclude scientific evidence may foretell an important role for the expert (i.e., helping courts to recognize potential sources of bias in medical texts or helping to determine whether a particular CPG is relevant to a case).

Whether engaged as a consulting or testimonial expert, the forensic expert can use his or her scientific knowledge to assist the attorney, who may want to know what CPGs are available in the context of the case at hand and whether there is any applicable evidence-based medicine (EBM) relevant to the case. Helping attorneys to learn about the applicable scientific literature that may be useful as evidence for either party in a case is part of the forensic expert's role.

The expert witness should consider whether to cite any CPGs in his or her opinion. The decision to rely on a particular medical text in forming an opinion should be carefully considered, as the selection or use of an unreliable or untrustworthy text may undermine the credibility of the expert's testimony. Lipton *et al.*[35] note several factors that may affect the validity or reliability of a medical treatise: fraud or scientific dishonesty in medical research, inappropriate use of medical statistics, conflicts of interest including the pressure to publish, and inadequate peer review. Even if CPGs are not cited, the expert should review which CPGs are available and should have a reasoned justification for not relying on them in reaching an opinion. For testimonial witnesses, the attorney or the court is likely to inquire as to the basis for the expert's opinion. Particularly if CPGs or other strong EBM do not form part of the basis for the expert's opinion, the scientific testimony may be vulnerable to a *Daubert* challenge, and experts should apply the scientific method to the extent possible in developing an opinion. Testimonial experts should familiarize themselves with the relevant CPGs, even if not citing them, as opposing counsel may use CPGs during cross-examination. Depending on the court and the facts of a particular case, the expert may testify about whether she relied on a particular CPG or medical learned treatise in formulating her opinion and whether a particular CPG is authoritative, respected, recognized, generally accepted, informed by scientific evidence, and relevant to the standard of care. In responding to such questioning, experts should be prepared to indicate the potential limitations of the CPG in question so that judges and juries do not take the guideline out of context.

In medical malpractice cases, forensic experts may be asked to offer an opinion as to whether a CPG is reliable and relevant to the clinical situation in the case.[71] Attorneys may seek the expert's assistance in authenticating a learned treatise as reliable and authoritative or may use a previously authenticated

treatise to question an expert during cross-examination. During cross, the expert is likely to be asked whether he is familiar with the treatise or article in question. To be familiar with a previously authenticated source, the expert need not acknowledge the text as authoritative or reliable, nor must he necessarily have read the document in question.[72] The expert may need to explain to the court why, although she is familiar with a text, she does not consider it trustworthy or relevant to the case.

During the discovery process, attorneys may be required to give notice to opposing counsel of an intent to introduce a learned treatise into evidence; an attorney may also attempt to have a treatise approved in advance (e.g., by judicial notice or request for admission). The forensic psychiatric expert may be helpful during this phase, in supporting a motion *in limine* during pretrial proceedings or by advising the attorney with regard to the reliability of particular CPGs or other medical learned treatises. Gutheil and Bursztajn[73] note that pretrial *Daubert* hearings have become an increasingly popular means of screening expert testimony for admissibility. CPGs and other professional resource documents may be useful for ensuring that an expert's testimony will survive a *Daubert* challenge. Similarly, an expert may be able to assist the attorney at this stage in discouraging the court from recognizing or accepting a particular document as a learned treatise.

For experts concerned about whether their testimony will trigger a *Daubert* challenge, Sageman[74] lists several red flags likely to trigger a challenge, such as subjectivity and lack of testing. When an expert's testimony triggers a *Daubert* hearing, Gutheil and Bursztajn offer recommendations for how forensic psychiatric experts may present their opinions so that they are more likely to survive the challenge.[75] The appropriate citation of relevant CPGs based on empirical, validated research and EBM should therefore strengthen an expert's testimony when used to inform and reinforce the expert's opinion.

CPGs and Scientific Research

Medical societies, such as the American Medical Association (AMA), the APA, and AAPL, as well as third-parties, such as HMOs and medical liability insurance providers, have created CPGs. In drafting, revising, and publishing CPGs, their creators rely on a variety of sources, including randomized controlled trials (RCTs), outcomes research, observational studies, consensus among leaders within a specialty, and expert advisors. CPGs of professional medical societies typically are designed to improve the care of patients. They are usually informed by medical expertise and empirical research and are driven by professional standards of care and the advancement of scientific knowledge. For these reasons, medical societies' CPGs may be more likely to be endorsed by medical expert witnesses as reliable. In contrast, CPGs of third-party payers (such as HMOs) are often aimed at cost-containment and may be used for utilization review.[6,68] Similarly, CPGs of malpractice insurance carriers may be intended more to lessen the risk of malpractice than to provide optimal care to patients. They may be viewed as less reliable because they are influenced by a view toward litigation. If physicians try to follow every CPG, they may find themselves trying to serve potentially conflicting goals: to provide the best quality care for their patients, to secure reimbursement for their services, and to avoid the risk of malpractice liability. This difficulty underscores the importance of clinical judgment in determining which CPGs to follow, if any.

Although a thorough discussion of EBM in the courtroom is beyond the scope of this article, it bears noting that one of the questions the expert should consider when evaluating a CPG or other medical learned treatise is whether the document meets the standards of EBM. As one scholar notes:

> CPGs are not the functional equivalent of EBM as some scholars have suggested. In fact, it is not only possible, but sometimes necessary to practice EBM without using CPGs. In addition, one can practice according to a CPG and not be practicing EBM [Ref. 76, p 488].

In evaluating a CPG for its application of EBM, one might ask, for example, whether the text supports its recommendations with meta-analyses, with double-masked, placebo-controlled, randomized trials or with other high-standard EBM. A CPG based on a lower standard of scientific reliability, such as expert consensus, may carry less weight in the courtroom and may do little to strengthen the expert's testimony. On the contrary, reliance on guidelines or documents that are not grounded in strong scientific evidence may weaken an expert's testimony. Furthermore, neglecting to incorporate relevant EBM into one's opinion could trigger a *Daubert* challenge or a zealous cross-examination.

In determining which CPGs or documents to cite, the expert should consider the impact of *Daubert* and

its progeny on the practice of medicine and scientific inquiry. The aftermath of *Daubert* and the growing importance of scientific articles and CPGs as evidence in the courtroom have already begun to influence the process and publication of scientific research. Peer reviewers caution authors to avoid prescriptive language and statements that may be taken out of context (in the courtroom). Some go so far as to warn the authors that statements should be cloaked in disclaimers to discourage the perception that they might be suggestive of a standard of care. More troubling is the growth of "litigation science," which scholars define as "the creation of a body of scientific studies generated for and funded by litigation" (Ref. 77, p 621). Law firms have a considerable interest in encouraging and using scientific research that will not only survive a *Daubert* hearing, but that will also tend to support the positions of the types of clients they serve. Concerns about the reliability of such research are similar to those raised for studies funded or otherwise sponsored by pharmaceutical or medical device companies.

With funding from law firms and other interested parties playing an increasingly influential role in scientific research, one troubling question is whether peer reviewers and scientific journal editors are able to identify such conflicts of interest and litigation bias when authors do not make full disclosures. In recent years, several prominent medical journals have come under criticism for publishing articles without uncovering and disclosing the authors' conflicts of interest.[78] Furthermore, peer review may not be as rigorous in practice as in theory,[21] particularly in less prestigious journals. Judges and juries typically are not well qualified to determine the trustworthiness of a particular journal's peer review process or to investigate whether authors may have concealed conflicts of interest (Ref. 77, p 621). The forensic expert could assist courts and attorneys in investigating such questions; one might look to the underlying support for a study, potential conflicts of interest, federal filings for research projects, or studies in European or international journals where the medical or scientific community may have had more time to collect longitudinal data. The forensic expert may also question whether contrary findings have been suppressed. Unfortunately, scientific research, particularly rigorous controlled studies, can be very expensive, so it may be difficult to find wholly unbiased published research that supports a forensic expert's opinion, even when the expert's opinion is based on sound scientific reasoning and well-accepted medical practice. Attorneys may need help in understanding this problem so that they can prepare adequately to argue a case.

In a study published in the *Journal of the American Medical Association*, Shekelle and colleagues[79] found that in a sample of AHRQ guidelines, over three quarters of the guidelines were in need of updating. They estimated that guidelines should be reviewed every three years to assess validity. Given the rapid pace of biomedical research and the relatively slow pace at which medical societies produce CPGs, forensic experts should be conscious of the possibility that a guideline in question may be outdated, even if it appears to have been revised recently. Testimony, like medical practice, should be informed not only by published treatises but also by professional experience and careful consideration of the relevant factors in a particular case.

Concluding Points

Guidelines in psychiatry and mental health may tend to be vague when compared with CPGs for other specialties and other medical conditions. Many guidelines in psychiatry emphasize the importance of clinical judgment, a factor that cannot be objectively measured through the lens of a practice guideline. These guidelines frequently outline the important elements of a full psychiatric examination, however, such as family history, comorbid conditions, psychiatric and medical history, current medications, and so forth. A forensic expert may be asked, for example, whether a defendant physician departed from the applicable standard of care when he or she failed to document a patient's family history of alcoholism. A CPG appropriate to the clinical scenario and specifying the importance of obtaining a full family history of all medical, psychiatric, and substance abuse conditions may support the expert's assertion that the defendant departed from the appropriate standard of care. If clinical conditions necessitate or justify a departure from recommendations in CPGs, forensic experts may help judges and juries to understand the complex nature of clinical decision-making and the importance of an individual patient's needs.

Forensic psychiatrists should remain conscious that CPGs may continue to play an important role in shaping medical practice. As one scholar explains:

> Proposals advanced to date for giving CPGs a greater role in medical malpractice litigation can be grouped into three

> categories. One group of reformers advocates requiring physicians and/or patients to enter into contracts *ex ante* to recognize a set of guidelines as constituting a binding standard of care. A second group has proposed that courts take judicial notice of CPGs as the standard of care, with deviations therefrom conclusively establishing negligence. A third group, by far the most influential, urges that compliance with CPGs should constitute an affirmative defense for physicians, but that deviations from CPGs should not be used as inculpatory evidence [Ref. 6, p 668].

Forensic experts who expect to testify or to file affidavits in conjunction with litigation may pay careful attention to emerging research, news, legislation, and policies relating to CPGs and their role in shaping the standard of care for medical practice. A sophisticated understanding of these elements can help the expert to gain a better understanding of the role of his or her participation in the legal process so that he or she may continue to act in the interests of improving patient care, advancing scientific knowledge for the benefit of humanity, and honoring her profession.

Appendix: Suggestions for Forensic Psychiatry Experts

Be prepared to elaborate on and explain any scientific document about which you may be questioned, as the jury will rely on your testimony, not on the document itself. Advise attorneys that you need time to review documents.

Fully review the contents of any medical learned treatise likely to be used by either side at trial. Be prepared to highlight any aspects of the guideline or document that may be debatable or questionable.

When evaluating scientific literature for use as evidence to support your testimony, be vigilant for signs of bias, sponsorship, or conflicts of interest that may affect the reliability of a document. Be prepared to explain why, beyond mere publication in a highly respected journal, a particular document should be considered reliable; consider indicators of scientific validity, such as double-masked, randomized controlled trials.

Be aware that courts may scrutinize a learned treatise, not only for reliability, but also for relevance. Do not cite articles in your testimony or deposition that are not directly relevant to the case at hand. Ensure that the conclusions you draw from CPGs or other learned treatises are directly supported by the literature itself or by reasoning that applies the scientific method.

During consultation with the attorney, it may be necessary to seek clarification as to which rules will control the admissibility of your testimony and the scientific literature you intend to cite. While many states' rules of evidence are similar to the Federal Rules of Evidence, not all jurisdictions apply the federal rules (see e.g., Ref. 80; some courts use state-specific rules of evidence or common law precedent.[36]

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