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11th Circ. Pushback On Professional Litigation Guides

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While some members of the plaintiffs' bar are touting the decision as a victory for malpractice plaintiffs, careful review of Adams v. Laboratory Corp. of America[1] reveals it is a narrow opinion with limited application. This article discusses the opinion, examines its limitations and suggests practical considerations for anyone contemplating the use of medical guidelines in litigation.

In Adams, the plaintiff and her husband brought negligence claims against Lab Corp. for allegedly failing to identify abnormal cells in a series of plaintiff's annual Pap smears, resulting in a delayed diagnosis of cervical cancer. The plaintiff offered the testimony of a pathologist who opined that Lab Corp. employees' failure to identify and flag abnormal cells breached the standard of care for cytotechnologists.

Lab Corp. challenged the admissibility of the plaintiff's expert's testimony based, in part, on her failure to conduct a blinded review as described in the Guidelines for Review of Pap Tests in the context of Litigation or Potential Litigation, as adopted by the College of American Pathologists and America Society of Cytopathology.[2] Finding that the expert's proffered testimony failed to use the methodology outlined in the CAP/ASC guidelines, the district court excluded the testimony and granted summary judgment in Lab Corp.'s favor.

The Eleventh Circuit revived the plaintiff's negligence claims after finding that the district court had committed an error of law. Applying the standards defined by Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579 (1993), and Federal Rule of Evidence 702, the court held that the CAP/ASC guidelines could not set the standard for admissibility or supplant the court's judgment and reversed the district court decision.

To evaluate the potential impact of the Eleventh Circuit's ruling, it is useful to consider the role of medical or clinical practice guidelines in litigation. Medical practice guidelines have become commonplace, with many medical specialties adopting guidelines intended to standardize quality of care and reduce variation in clinical practices.[3] For example, the American Cancer Society has adopted guidelines for Cervical Cancer Screening that outline when and with what frequency women should have Pap tests based on the patient's age and relevant risk factors.[4] The American Cancer Society has also adopted similar guidelines regarding who should receive colorectal cancer screening and what screening

methods are recommended.[5] As the adoption of these guidelines has increased so has their role in litigation.

In medical malpractice cases, where the central issue hinges on the applicable standard of care, practice guidelines regularly play a role. The law on the permissible use of practice guidelines varies by jurisdiction, but most commonly allows their use to support expert testimony.[6] Plaintiffs and defendants alike may point to guidelines as either exculpatory or inculpatory evidence regarding alleged violations of the standard of care.

Perhaps in response to the growing use of medical testimony in malpractice cases, some medical organizations started enacting litigation practice guidelines. Unlike the medical practice guidelines, these litigation guidelines do not recommend clinical practices for patient care but instead dictate when and how members of an organization should participate in the legal process as medical experts. Largely, these litigation guidelines set out the ethical concerns facing medical expert witnesses. This makes perfect sense, as the medical profession is self-regulating and medical organizations have an interest in their members' conduct.

The problem identified by the Eleventh Circuit is that some of these guidelines, in particular those raised in the Adams case, purport to describe legal standards governing the admissibility of evidence rather than recommendations for patient treatment. As recognized by the Eleventh Circuit, this runs afoul of the role courts and juries play.

Malpractice claims are based in negligence, a legal concept to be determined in a court of law. As noted by the district court, the CAP/ASC guidelines define a standard for this legal concept: "Negligence should not be inferred unless there is a consistent finding by the reviewers that the laboratory failed to identify clinically significant abnormalities."[7] Furthermore, what evidence is admissible to establish negligence is within the province of the court, and a determination of what constitutes negligence in a matter for the jury. Yet, the CAP guidelines dictate that "[a] violation of a reasonable prudent practitioner standard of practice based on how specific Pap tests were screened and interpreted can only be established through an unbiased blinded rescreening review process."[8]

In reversing the district court, the Eleventh Circuit stated, "Despite the skewed nature of the CAP's and ASC's guidelines, the district court expressed no skepticism about them, referring to their insistence on blinded review as 'the litigation standard within the practice of pathology.' But neither Daubert nor Kumho permit a scientific or medical community to define a 'litigation standard' that applies when its members are sued."[9] According to the court, in adopting these guidelines, "CAP and ASC moved away from disinterested scientific inquiry and into litigation policy to serve their members' own interests."[10] The Eleventh Circuit concluded that the district court's reliance on these guidelines as setting the standard for the profession, and for admissibility of expert testimony, was manifest error.

The court's holding focused on two fact-specific issues that will render most professional guidelines distinguishable from this case.

First, the court held that the specific guidelines at issue were "litigation guidelines," not practice guidelines addressing "how cytotechnologists should go about their duties in examining slides, but instead on how courts should go about their duty to adjudicate claims against cytotechnologists."[11] The court reasoned that the guidelines were not "objective, scientific findings" but instead were "policy proposals to limit how courts can find members of the organization liable for professional negligence when they are sued."[12]

The court recognized the potential for "hindsight bias" resulting from the nonblinded review of Pap tests, but held that "[b]ias in an expert witness's testimony is usually a credibility issue for the jury."[13] The court reasoned that if the guidelines were applied as written, expert testimony would be excluded unless the potential for bias was completely eliminated.[14] This would impose an additional hurdle to the admissibility of expert testimony that is not required by Daubert or the federal rules. The court concluded that imposing such a standard would "be a radical reworking of Rule 702" and held that it was an abuse of discretion.[15]

Second, the guidelines set requirements that were, on their face, one-sided. For example, the guidelines describe, in detail, the methodology by which Pap smear findings could be challenged as falling below the standard of care but completely failed to require a similar standard for experts testifying regarding compliance with the standard of care. The court found that "the purpose of the guidelines is to raise the bar only on the plaintiffs' side of the courtroom."[16]

It appears that the district court simply went too far. It was the wholesale adoption of the guidelines, without further analysis, that most concerned the Eleventh Circuit.[17] The court found that "litigation policy" does not equate either with "general acceptance" under Daubert[18] or "the practice of an expert in the relevant field" under Kumho,[19] and can therefore not form the basis of an admissibility challenge.[20]

While the Eleventh Circuit's opinion may raise questions about the weight a court may afford professional guidelines, it does not prohibit courts from considering them in the context of standard of care cases. The court simply held that the district court had improperly supplanted the role of the court, and the jury, by "delegating to industry groups the gatekeeping duties of the courts."[21]

Litigants seeking to rely on guidelines should carefully consider when and how they are presented to the court. Do the guidelines set forth objective, scientific methodologies? Are they intended to standardize patient care or do they seek to dissuade litigation? How are the guidelines used in the daily practice of clinicians in that practice area? Do the guidelines support expert testimony or do they purport to set the applicable standard of law? Considering these and similar questions should allow litigants to determine how best to use favorable guidelines without transgressing Adams.

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[1] Adams v. Lab. Corp. of Am., 2014 WL 3724190 (11th Cir. July 29, 2014).

[2] http://www.cytopathology.org/guidelines-for-review-of-gyn-cytology-samples-in-the-context-of-litigation-or-potential-litigation/ ; http://www.cap.org/apps//cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt%7BactionForm.contentReference%7D=policies%2Fpolicy_appZ.html&_state=maximized&_pageLabel=cntvwr (last visited on 9/26/14).

[3] “The Role of Practice Guidelines in Medical Malpractice Litigation,” AMA Virtual Mentor, Vol. 13, Number 1: 36-41 (Jan. 2011).

[4] http://www.acog.org/~/media/Districts/District%20II/PDFs/USPSTF_Cervical_Ca_Screening_Guidelines.pdf (last visited on 9/26/14).

[5] http://www.cancer.org/cancer/colonandrectumcancer/moreinformation/colonandrectumcancerearlydetection/colorectal-cancer-early-detection-acs-recommendations (last visited on 9/26/14).

[6] Id.

[7] Adams v. Lab. Corp. of Am., 2012 WL 370262, at *13 (N.D. Ga. Feb. 3, 2012) (quoting the CAP guidelines).

[8] Id. at n.8 (emphasis added).

[9] Adams, 2014 WL 3724190, at *7.

[10] Id. at *7.

[11] Id.

[12] Id.

[13] Id. at *6.

[14] Id.

[15] Id.

[16] Id.

[17] Id.at *7.

[18] Daubert v. Merrill Dow Pharm., Inc., 509 U.S. 579 (1993).

[19] Kumho Tire v. Carmichael, 526 U.S. 137 (1998).

[20] Adams, 2014 WL 3724190, at *9.

[21] Id.
