

## Standards

### **Questions Swirl Over Industry Guidelines; 'Stealth Tort Reform' or Valid Self-Regulation?**

**T**he Eleventh Circuit's recent sharp rebuke of "biased" professional standards in a Georgia medical malpractice case has energized the plaintiffs' bar, which calls the industry guidelines a form of "stealth tort reform" and a threat to plaintiffs in product liability and other cases.

But are these decade-old standards, which seek to diminish the influence of plaintiffs' experts in courtrooms, a valid form of self-regulation, or perhaps even like the filing of an amicus brief by an interested professional group, as some defendants' attorneys say?

Interviews with 10 experienced attorneys and legal experts following the U.S. Court of Appeals for the Eleventh Circuit's July 29 reproach of "one-sided" litigation guidelines advanced by the College of American Pathologists (CAP) and the American Society of Cytopathologists (ASC) reveal diverging views, but also practical advice on the path forward in the aftermath of *Adams v. Lab. Corp. of Am.*, 2014 BL 209312, 11th Cir., No. 13-10425, 7/29/14 (14 EXER 349, 8/4/14).

Charles M. Cork, who represented the plaintiff in this case, said it was particularly problematic that the guidelines here were a one-way street: They attempted to limit the expert evidence plaintiff Christina Adams could use to prove lab errors delayed the treatment of her cervical cancer, but not the evidence that the industry could use in its defense.

Scores of medical and professional groups issue benchmarks, usually to police the qualifications of professional members or to establish best practices within the industry. The guidelines here, however, went beyond attempting to establish the standard of care for interpreting PAP smears, Cork, who practices in Macon, Ga., said in an Aug. 27 e-mail.

"They attempted to control how the liability of the industry would be established in court, mainly by limiting the evidence that could be used against the industry," he said.

But Jack R. Bierig, a partner at Sidley Austin in Chicago and a noted health care lawyer whose clients include the American Medical Association and the American Dental Association, said the Eleventh Circuit got it wrong in criticizing CAP and ASC for trying to guide expert witnesses on proper medical procedures, and in

### **Arguments in a Nutshell**

#### **Guidelines Supporters:**

- Goal was fair, reliable testimony
- Societies exercised free speech rights
- Standards weren't binding

#### **Guidelines Opponents:**

- Applied only to plaintiffs' experts
- Invaded province of judges
- Akin to tort reform

"completely rejecting" the views of those associations on key policy issues in medical malpractice cases.

Defendants' attorney Todd W. Smyth, with Smyth Whitley in Charleston, S.C., who also specializes in health care law, said the guidelines were designed to help the medical sub-specialty boards police their members when they testify in legal proceedings so that the testimony is "fair, reliable and represents the consensus of understanding within their community."

Smyth, the chairman of the DRI's Medical Liability and Healthcare Committee, told Bloomberg BNA in a Sept. 3 e-mail that there is "wisdom" in the CAP and ASC's guidelines because they require a blinded review by medical experts—meaning the reviewer should not already know the results.

Because the plaintiff's expert in the underlying case already knew a patient was diagnosed with cancer before looking at the first slide, the expert "was practically bound to identify some evidence to support what she knew to be the case or risk possibly appearing incompetent herself. In my estimation, the guidelines are simply trying to prevent the pallor of bias," Smyth said.

A spokesman for the College of American Pathologists told Bloomberg BNA Aug. 29 that it's "reviewing its policy" in light of *Adams*. Dr. Bruce Williams, the chair of the CAP's Council on Scientific Affairs, will be involved in the process, the group's communications director, Joe Schramm, said in an e-mail.

The ASC did not respond to Bloomberg BNA's Aug. 27 request for comment.

**'Rallying Cry' for Plaintiffs' Bar.** The spirited defense of the industry guidelines by Bierig, the general counsel of the CAP from 1980-2005, when he helped shape an earlier version of the standards, together with Smyth, comes as the guidelines face a withering attack from the plaintiff's bar for seeking to restrain malpractice cases by increasing the burdens on injured plaintiffs.

Plaintiffs' attorney Lyle Griffin Warshauer said the "CAP Guidelines for Review of Pap Tests in the Context of Litigation or Potential Litigation," and the similar version adopted by the ASC, "Guidelines for Review of GYN Cytology Samples in the Context of Litigation or Potential Litigation," were part of an "unprecedented attempt to limit access to the courts for women who are injured because of the negligent misreading of Pap smears."

The Warshauer Law Group in Atlanta filed an amicus brief in *Adams* and in an earlier case in state court in Georgia.

Warshauer, a senior partner, told Bloomberg BNA in an Aug. 28 e-mail that there are no similar litigation standards from any other industry or professions.

She said the two guidelines trace their roots to 1998, and were "promulgated solely for litigation." They were designed to "usurp the trial court's function as a gatekeeper for admission of expert testimony and serve no legitimate purpose," she said.

Patrick A. Malone, a prominent plaintiffs' malpractice attorney in Washington, said the Eleventh Circuit's

## Quick Takes From Attorneys

**Jack R. Bierig:** Appeals court went too far.

**Charles M. Cork:** Guidelines are "stealth tort reform."

**Jeffrey J. Greenbaum:** Standards "invaded province of the court."

**Gregory P. Joseph:** "No role" for one-sided guidelines.

**Prof. Aaron S. Kesselheim:** Ruling sends "strong message to societies."

**Patrick A. Malone:** Ruling a rallying cry for plaintiffs' bar.

**Thomas E. Peisch:** Trial court "muddied up" *Daubert* dictates.

**Douglas G. Smith:** Ruling was a "narrow" one.

**Todd W. Smyth:** There was "wisdom" in guidelines.

**Lyle G. Warshauer:** Opposes "unprecedented attempt to limit access to courts."

compelling ruling is operating as a rallying cry for the plaintiffs' bar.

These guidelines are "unique" in the way they seek to alter the burdens of proof in malpractice cases, he told Bloomberg BNA Sept. 2. He predicted *Adams* will be influential with other courts as "a reminder not to

## CAP 'Guidelines for Review of Pap Tests in the Context of Litigation or Potential Litigation'

Pap test slides being assessed in conjunction with litigation or potential litigation should be reviewed without knowledge of clinical outcome and in an environment that simulates the normal screening practice. A finding of a false negative Pap test is not necessarily evidence of practice below the standard of care. A physician-witness should have significant experience in cytopathology and should not be compensated contingent upon the outcome of the trial. Potential parties to litigation should strongly consider mediation or non-binding arbitration by an expert panel prior to proceeding with civil litigation.

...

In the context of litigation and potential litigation, there should be an unbiased and scientific method for review of questioned cases that is fair to both the patient and the laboratory. To help attain this objective, the College offers the following guidelines for use by courts and attorneys:

■ The finding of a false negative in a gynecologic cytology

sample is not, by itself, proof of practice below the standard of care. A false negative gynecologic cytology finding can occur—without any negligence—as a result of the subjectivity involved in evaluating difficult cases or as a result of the inadequacy of the specimen.

...

■ Before asserting a violation of the standard of care, complainant should first have the Pap test slides assessed by qualified reviewers without knowledge of clinical background and in an environment that simulates normal screening practice. Specifically, such slides should be subjected to an unbiased screening process that includes the contested case material as one or more of a substantial number of normal and abnormal gynecologic cytology samples. The best process is to have the evaluation conducted by several qualified reviewers. Negligence should not be inferred unless there is a consistent finding by the reviewers that the laboratory or practitioner failed to iden-

tify clinically significant abnormalities.

■ The standard of care should be that of the reasonable and prudent practitioner. Focused review, or review with knowledge of subsequent development of carcinoma, biases the objectivity of the review. Unless the review is blinded, it cannot establish a deviation from the standard of practice.

■ Professional expert witnesses who do not have significant experience in cytopathology are not qualified to express an expert opinion on the standard of care. Instead, a court should rely upon the testimony of expert physician witnesses who have, at a minimum, the following qualifications:

...

■ To adjudicate the performance of a cytotechnologist, the court may alternatively rely upon the testimony of expert cytotechnologist witnesses who have, at a minimum, the following qualifications:

...

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defer to professional groups with interest in the outcome of litigation.”

**‘Biased’ Guidelines Slammed by 11th Circuit.** The Eleventh Circuit’s July 29 opinion in *Adams* sharply criticized the groups’ guidelines (CAP standards excerpted below), which were cited as authoritative by a trial court in throwing out the pro-plaintiff testimony of an expert who has trained cytotechnologists for more than 40 years on how to study cells microscopically for evidence of disease.

In reinstating that testimony and allowing *Adams* to proceed with her malpractice case, the appeals court said it was difficult to imagine how the experience of the excluded expert—Dr. Dorothy Rosenthal was the former director of cytopathology for the Johns Hopkins Medical Institutions in Baltimore—could’ve been more extensive and relevant, or contributed more to the reliability of the methodology she used in the case.

The three-judge appellate panel didn’t stop there; it savaged the guidelines as biased policy proposals intended to limit the liability of organizational members who may be sued for professional negligence.

The guidelines of the CAP and ASC “moved the groups away from disinterested scientific inquiry and into litigation policy” to serve their members’ own interests, the court said. It said the effort was the “first time that an industry group has promulgated a set of guidelines that attempts to define and limit the evidence courts should accept when the group’s members are sued.”

The appeals court also warned that allowing professional associations to posit “one-sided” standards would encourage potential defendants in other high stakes fields to seek similar advantages, such as pharmaceutical companies in product liability cases.

Warshauer told Bloomberg BNA that the CAP and ASC litigation guidelines weren’t always “one-sided.” As originally set out in 1998, the CAP standards were to apply to “both plaintiff and defense consultants and experts,” but were changed at some point.

And when ASC adopted its version of the guidelines in 2000, the group “dropped the requirement that experts who defend its members should reach their opinions in an unbiased or nonprejudicial manner,” Warshauer said.

Later, in 2007, an ASC committee recommended amending the guidelines to be “more fair to both sides.” However, ASC’s Ethics Committee “rejected the balanced proposal,” Warshauer said, “because it ‘could have the unintended consequence of weakening the current litigation guidelines and could make defense of some cervical cytology specimens more difficult.’”

In a 2007 article in *CAP Today*, an association publication, Bierig was asked about the then-evolving guidelines. In comments that foreshadowed the debate now, he said a “key issue is ensuring that the guidelines do not seem biased toward the defendant, which can be a risk—whether reality or just perception—when a physician group develops guidelines on expert testimony.”

In that article, “*Expert Witness Guidelines: Pathologists Given New Order in the Courtroom*,” Bierig continued, “If this document were perceived as a document designed to protect pathologists in malpractice cases, the courts wouldn’t give it any credence.”

Warshauer noted that the guidelines have made their way into other cases, most recently *LaVelle v. Lab. Corp. of Am.*, Ga. Ct. App., No. A13A1722, 3/28/14.

In *LaVelle*, a Georgia appeals court March 28 scolded a trial judge for ruling that the blinded reviews advocated by the CAP and ASC were the only methodology that an expert could use to reach an opinion on a breach of the applicable standard of care.

That 5-2 ruling, which contrasted with the pro-defendant 2012 trial court finding in *Adams*, found “no legal authority—legislative or judicial—that directs the specific methodology an expert must use to establish a breach of the standard of care in a professional malpractice case.”

**Did Guidelines Go Too Far?** Aaron S. Kesselheim, an attorney and associate professor of Medicine at Harvard Medical School in Cambridge, Mass., said guidelines like those of CAP and ASC are a way for professional societies to self-regulate. There are probably many members of the society who get involved with litigation, so some members demand from the society “consensus-driven guidelines for proper behavior,” he said.

But the district court should never have used the guidelines in the way it did—which was as “a hard and fast exclusionary rule that would take the place of the judge’s judgment,” he said in an Aug. 27 e-mail.

Kesselheim said the ruling sends a “strong message to societies about guidelines that ‘cross the line’ and directly seek to position themselves inside litigation processes (which this court saw as beyond the scope of the medical professional societies) as well as to district courts about relying solely on these guidelines as the only way of assessing expertise.”

Kesselheim, who is also affiliated with Harvard’s School of Public Health and has written extensively on policy issues involving expert testimony in malpractice cases, said the Eleventh Circuit was correct in criticizing the guidelines to the extent that they “imply application only to plaintiffs’ experts.”

“The evidence-based practices expressed in such guidelines should be applicable to all parties,” he said.

Evidence expert Gregory P. Joseph, of Joseph Hage Aaronson in New York, agreed. “One-sided” guidelines shouldn’t play any role in litigation, Joseph, a former president of the American College of Trial Lawyers and past chair of the American Bar Association’s Section of Litigation, said.

Although many organizations set standards of care, and courts respect them, these guidelines “were not unbiased” in the eyes of the court, Joseph said in an Aug. 21 e-mail. They were “skewed” in favor of members who were being exposed to liability as defendants, and weren’t grounded in the “scientific acceptance” touchstone established by the U.S. Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), he said.

The ruling has also divided defendants’ attorneys, with several saying the guidelines may have overreached.

Defendants’ attorney Jeffrey J. Greenbaum, a member of Sills Cummis & Gross in Newark, N.J., and a former ABA liaison to the U.S. Judicial Conference Advisory Committee on Civil Rules, said the CAP and ASC guidelines didn’t appear to set standards for the profes-

## Practical Advice

### Litigators:

- Tell court why guidelines should be accepted.
- Use offensively to challenge evidence.
- Use defensively to bolster experts.

### Associations:

- Revisit guidelines every few years.
- Apply standards equally, for all experts.
- Don't use the word "litigation."

sions in question for performing their work in general, but "seemed limited to testifying in litigation."

The court appropriately rejected the efforts to "invade the province of the court in determining what *Daubert* requires," Greenbaum said in an Aug. 27 e-mail.

Thomas E. Peisch, a defendants' attorney and a partner at Conn Kavanaugh Rosenthal Peisch & Ford in Boston, agreed. The Eleventh Circuit got it "exactly right" in rejecting the guidelines, he told Bloomberg BNA in a Sept. 1 e-mail.

"*Daubert*, after all, EXPANDS the universe of admissible expert testimony and does not restrict it. In my view the Adams trial court applied an inappropriately narrow view of *Daubert* in striking Dr. Rosenthal's testimony," he said.

While any professional society should be free to develop its own standards of conduct, those standards are not a substitute for what *Daubert* requires—that the scientific evidence be reliable, he said. "The trial court muddled up that key point," he said.

Peisch said Rosenthal's expert opinion should have been attacked by vigorous cross-examination, both as to the standards of conduct requiring blind studies and as to Rosenthal's "philosophical bent." That is what *Daubert* contemplates, he said.

Defendants' attorney Douglas G. Smith, a partner at Kirkland & Ellis in Chicago, and author of a Bloomberg BNA litigation portfolio on scientific evidence, said the ruling was a narrow one, and focused heavily on aspects of the guidelines that may not be generalizable to other guidelines that might come up in future cases.

"The court's decision should not be read as condemning all such guidelines. Rather, the court appeared to focus on particular aspects of the guidelines before it that it believed rendered them a poor basis on which to base the court's *Daubert* decision," he told Bloomberg BNA in a Sept. 2 e-mail.

**Guidelines Have Strong Defenders.** Defending the guidelines, Bierig said the standards here sought to show a potential expert witness in a negligence case stemming from a PAP test how to conduct a retrospective review of the slides in question. It also offered the groups' perspective on what a court should consider in evaluating testimony by an expert witness in this sort of litigation.

Bierig said the court overstepped when it questioned the motives of the two medical associations as to the proper procedure for reviewing slides.

The guidelines were issued to guide practitioners who review PAP tests and to influence courts as they consider the reliability of expert testimony, and "both objectives are perfectly proper," Bierig said in an Aug. 22 e-mail.

"In some senses, the issuance of guidelines on how a court should consider expert testimony is no different from the filing on an amicus brief that sets forth the position a professional society and suggests a framework for the decision of the case," Bierig said.

"There was nothing secret or illicit about anything that the societies did. In essence, all that they did was exercise their First Amendment rights to speak out on an issue that they regard as important," he said.

CAP is also a Sidley client, but Bierig told Bloomberg BNA he has done very little work for them since 2005.

Health care attorney Smyth said the Eleventh Circuit never went "so far as to say the guidelines are inadmissible, but rather it held that the failure of the expert to adhere to the CAP and ASC guidelines in this case was not, in and of itself, sufficient grounds to exclude the expert from testifying."

Smyth said he also didn't believe the guidelines were an attempt by the groups to influence policy improperly. The "impetus behind these guidelines was to ensure that professional witnesses provide testimony that is fair, reliable and represents the consensus of understanding within that particular community of practitioners," he said.

"Understand, too, that not all experts who testify in legal proceedings have agreed to be bound by these guidelines which, of course, begs the question of why wouldn't they? Do they disagree with a consensus position or do they want the freedom to use their own methodology, testify however they like and not worry about being held accountable to their peers?" he said.

Smyth predicted that the ruling would have "very narrow" application in other cases because it really deals with only one specialty's guidelines, cytopathology.

"I do not think the opinion purports to criticize guidelines in general, but rather simply dealt with the ones before it in this case," he said.

**Ethical Boundaries Debated.** Warshauer contends that by sharply criticizing the district court for "abdicated its gatekeeping responsibilities" to the Laboratory Corp. of America, the defendant in the *Adams* case, the Eleventh Circuit offered "compelling guidance to trial courts throughout the country that biased guidelines written by self-interested trade groups have no place in what is supposed to be the court's neutral analysis of whether an expert's opinions are reliable and thus admissible."

Peisch, who specializes in the defense of professional malpractice cases, said he also believed that ethical boundaries were crossed when the two organizations "tried to influence an important evidentiary aspect of highly-charged litigation under the guise of a professional 'standard.'"

The "two sets of 'standards' appear to have been designed more to protect members from lawsuits than to assure scientific integrity," he said, and noted that the

“standards” may have “fared better had the word ‘litigation’ not appeared in them.”

But Bierig and Smyth said neither CAP nor ACS crossed any legal or ethical boundary. “My guess is that any professional society that issues a guideline realizes that it may be adopted as the standard of care, and some hope that the guideline will be so used. But I see absolutely nothing wrong with that,” Bierig said.

“In the end, it is for the court, not the professional society, to determine what the standard of care is. All that the professional society is doing is setting forth its position.”

Smyth said he also didn’t see any ethical breaches by the two groups. “I see the gravamen of this decision being about the threshold admissibility and reliability of expert evidence,” he said.

Bierig said that as long as guidelines are adopted after careful consideration and in accordance with fair procedure, he sees no ethical concerns. “Of course, one lesson from this decision is that a professional society which promulgates a guideline which it hopes will be adopted should document the basis for its positions to the extent that it can.”

Kesselheim agreed that it’s ethical for medical professional societies to create guidelines that seek to influence the standard of practices of their members. In *Adams*, the groups were backing the use of “blinded reviews” of PAP smear slides. He also said it was reasonable for professional societies to create guidelines that may end up being used in court.

On the other hand, Kesselheim said it would be “unethical” for professional societies to pass guidelines or rules that go further, and prevent members from getting involved in the litigation process, because it’s also ethical—and “indeed essential”—for doctors to be available to serve as plaintiffs’ and defendants’ experts.

He said he didn’t think these guidelines went that far, and to the extent that they only seem to apply to one side, “I think that’s something that can be fixed.”

Kirkland & Ellis’s Smith said the guidelines “certainly seemed like they were intended to influence policy, and certainly there is nothing improper about a professional organization issuing principles or guidelines that it believes represent the accepted approach within the relevant scientific community.”

Nonetheless, such guidelines are not binding on the courts, and courts may well reject them if they believe that they constitute a flawed basis on which to judge the reliability of expert testimony, Smith said.

**Slippery Slope?** Cork said that if these guidelines were “allowed to be decisive, every other industry could substantially immunize itself by adopting similar guidelines.”

This concern over future implications was stressed by the appeals court, which wrote that if the CAP and ASC can define what constitutes admissible expert testimony in their members’ professional negligence cases, “then there is no apparent reason why other groups whose members face lawsuits cannot do the same.”

The court pondered, “why couldn’t pharmaceutical companies adopt guidelines setting high standards of proof for establishing that a plaintiff’s injury was caused by a given drug and justify doing so based on their experience with the complex nature of pharmacology and their expertise in the field? Why couldn’t an association of prison guards and wardens presume to de-

fine the meaning of ‘deliberate indifference’ or the requirements for admission of evidence in custodial litigation.”

Warshauer said that to the extent that other groups might advocate for the use of similar “one-sided” litigation guidelines to influence the admission of evidence in civil actions, the Eleventh Circuit decision “should put those efforts to rest.”

Kesselheim said both sides have reasonable arguments, and that *Adams* doesn’t necessarily portend a “sea change in the role these guidelines play, or in medical professional societies’ interest in them.”

The medical professional societies are right to try to develop guidelines that might help members determine standard of care for reviewing slides in litigation contexts; in this case, “because it’s true that blinded review is a really good way of trying to exclude bias,” he said.

“However, I also agree that steps taken that don’t align with the guideline should not necessarily exclude a potential expert. They’re obviously something that can be used to impeach and something juries may want to take into account, but there might be reasonable explanations for behavior that does not comport with the guideline, and that seems like something that could come out in the trial,” he said.

**Advice for Litigators and Groups.** So what should litigators and professional associations concerned about the proper role of litigation guidelines do in light of *Adams*?

**For litigators:** Bierig said litigators seeking to use industry guidelines in their case should now:

- discuss any applicable guideline with their experts to make sure that each expert is aware of the guideline,
- review the extent to which the litigator and the expert agree with the guideline, and decide whether they want to follow it, and
- be prepared to tell the court why (depending on their view) a particular guideline should, or shouldn’t, be accepted by the court as the standard of care, or otherwise probative value.

Smyth said each case is different, but for litigators, “offensively, I think guidelines such as these can and should be raised initially as an evidentiary challenge as was done in this case or, if that is not appropriate, then they could be part of a vigorous cross-examination designed to demonstrate the opposing expert’s methodology or conclusions do not comply with the consensus in the field.”

Defensively, the guidelines can be used to “bolster your own expert’s methodology by showing that his/her analysis does comport with the guidelines, thus adding a degree of credibility to the expert’s analysis,” Smyth said.

**For professional societies:** As for professional societies, Bierig said they should revisit any guidelines they may have every two or three years to make sure that they reflect changes in the state of knowledge and practice—and continue to represent the best views of the society that issued them.

As for CAP and ASC, the issuing societies might want to determine, in light of *Adams*, whether they continue to believe that the guidelines are correct.

“To the extent that they conclude that the guidelines are correct, they might want to articulate reasons or

provide citations that support the positions expressed,” Bierig said.

“To the extent that they conclude that the guidelines are incorrect or outmoded, they should modify or withdraw the guidelines,” he said. “But nothing in the decision persuades me that there is anything wrong with a professional society expressing its view in the form of guidelines.”

Smyth said that one could argue that had the guidelines here “imposed similar requirements on both plaintiff and defense experts that the appellate court may have reached a different conclusion, but that is speculative.” As a general matter, however, “the more balanced the guidelines are written, the greater the chances of them being applied by a court.”

Courts are often “very reluctant to enforce anything they view as draconian or inequitable,” he said.

Pesich said he would advise a professional society not to use the word “litigation” in any professional standard or guideline.

“It seems to me that if a society wants to recommend or impose a particular course of conduct on a member, it can do so without using that word,” Pesich said.

Smith said the ruling makes clear that in crafting similar guidelines professional associations should seek to avoid the appearance of bias, noting the court “focused on the fact that the guidelines were expressly aimed at plaintiff experts only.”

In addition, the appeals court noted that the guidelines seemed to be drafted in a way to further the self-interest of the association’s membership, Smith said.

“To the extent professional associations can avoid the appearance of bias in drafting such guidelines it is more likely that courts will rely upon them in rendering decisions under Federal Rule of Evidence 702 and *Daubert*,” he said.

Kesselheim said that in light of the Eleventh Circuit ruling, “it would be reasonable for professional societies to make sure their guidelines are not inappropriately directed at one side of the litigation ledger or the other.”

**For courts:** As for how other courts should handle similar guidelines, Kesselheim said guidelines like these should be taken for what they are: “consensus statements (although such a determination would require some background examination to determine whether they truly are the consensus of a large group, as opposed to created by a small cadre of practitioners) made by experts in the field.”

Courts, however, must evaluate the context of the plaintiff’s and defendant’s expert testimony to determine to what extent the practices were nonetheless reliable even if they may have varied somewhat from the guidelines.

“Guidelines are just guidelines, they’re not dictates,” he said.

BY BRUCE KAUFMAN