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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 13-10425

D.C. Docket No. 1:10-cv-03309-WSD

CHRISTINA NICOLE ADAMS, CHRISTOPHER L. ADAMS,

Plaintiffs-Appellants,

versus

LABORATORY CORPORATION OF AMERICA,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Georgia

(July 29, 2014)

Before CARNES, Chief Judge, MARTIN and GARZA,* Circuit Judges.

PER CURIAM:

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*Honorable Emilio M. Garza, United States Circuit Judge for the Fifth Circuit, sitting by designation.

Christina and Christopher Adams ("the Adamses") filed a lawsuit against Laboratory Corporation of America ("LabCorp"), alleging that its cytotechnologists were negligent in failing to identify abnormalities in Ms. Adams's Pap smears and that this negligence caused a delay in her cancer diagnosis. LabCorp moved to exclude the testimony of Dr. Dorothy Rosenthal concerning the alleged breach of the cytotechnologists' standard of care and moved for summary judgment based on the resulting absence of evidence regarding the standard of care. The district court granted both motions, and the Adamses now appeal. We reverse the district court's evidentiary ruling, vacate the grant of summary judgment to LabCorp, and remand for further proceedings.

I.

In the 32-month period from January 2006 to September 2008, Ms. Adams received five Pap smear tests. Her doctor took scrapings from her cervix, put them on a slide, and sent that slide to LabCorp for review to determine if there were abnormalities in the cells on the slide. Ms. Adams was not diagnosed with cervical cancer until August 2009, when she went to her doctor complaining of vaginal bleeding. By then, the cancer had metastasized in Ms. Adams's lymph nodes. The Adamses brought suit against LabCorp, alleging that, between 2006 and 2008, the LabCorp employees who viewed slides of Ms. Adams's cells failed to properly identify the abnormal cells on those slides that indicated precancerous conditions

or cancer. They contend that those mistakes by LabCorp's employees delayed the diagnosis and treatment of her condition for several years until after her cancer had developed and metastasized.

LabCorp's method of reviewing samples is as follows. A cytotechnologist reviews each Pap smear slide by examining it under a microscope. Cytotechnologists are not doctors; they are laboratory professionals trained to examine cells using microscopes and to recognize cells that appear abnormal.[1] If any of the cells on the slide has precancerous abnormalities or other indications of cancer, the cytotechnologist sends the slide to a pathologist[2] for review. If the cytotechnologist does not see or recognize any abnormal cells, no pathologist reviews the slide.

The Adamses retained Dr. Rosenthal as an expert witness to testify about whether LabCorp's employees breached the standard of care for cytotechnologists when reviewing Ms. Adams's slides. Dr. Rosenthal's qualifications are extensive. She has been a Professor of Pathology at the Johns Hopkins School of Medicine since 1995 and served as Director of Cytopathology for the Johns Hopkins Medical Institutions from 1995 to 2003. She has two board certifications from the

[1] *See* 1 *Exploring Tech Careers* 215 (4th ed. 2009); *see also* 42 C.F.R. § 493.1483 ("Standard: Cytotechnologist Qualifications").

[2] A pathologist is a doctor who specializes in "the structural and functional manifestations of disease." *Dorland's Illustrated Medical Dictionary* 1416 (31st ed. 2007).

American Board of Pathology: one in Anatomic and Clinical Pathology, and another described as an Added Qualification in Cytopathology.[3] She served on the initial task force that developed the Bethesda System terminology, which is the classification system that pathologists and cytotechnologists—including those working at LabCorp—use for reporting Pap smear results.[4] She testified in her deposition that she also has "over 40 years of experience of training cytotechs."

Dr. Rosenthal formed her opinion by traveling to Atlanta and reviewing Ms. Adams's slides at LabCorp's laboratory. She spent about 90 minutes examining Ms. Adams's Pap smear slides, using the same model of microscope that LabCorp's cytotechnologists used. She did not mix in slides from other patients, and she already knew that Ms. Adams had been diagnosed with cervical cancer. Dr. Rosenthal ultimately concluded that LabCorp's cytotechnologists' review of Ms. Adams's slides fell short of the applicable standard of care by failing to identify abnormal cells that should have been identified.

After the discovery period had closed, LabCorp moved to exclude Dr. Rosenthal's testimony concerning the alleged breach of the cytotechnologists' standard of care. In its motion, LabCorp contended that Dr. Rosenthal's review of

[3] Cytopathology is "the study of changes in cells in disease." *Dorland's Illustrated Medical Dictionary* 474 (31st ed. 2007).

[4] *See generally* World Health Organization, *Comprehensive Cervical Cancer Control: A Guide to Essential Practice* 39 (2006).

Ms. Adams's Pap smear slides was tainted by an unreliable methodology. Assuming that Dr. Rosenthal's testimony was excluded, LabCorp also moved for summary judgment based on the absence of evidence regarding the cytotechnologists' standard of care, an essential element of the professional negligence claim.

The district court granted LabCorp's motion to exclude Dr. Rosenthal's testimony based on its conclusion that her methodology did not meet the reliability requirement of Federal Rule of Evidence 702.[5] The court characterized her methodology as an *ipse dixit* assessment that could not be meaningfully reviewed by other experts. It insisted that she should have used a blinded review to evaluate Ms. Adams's slides,[6] citing the litigation guidelines approved by the College of American Pathologists ("CAP") and American Society of Cytopathology ("ASC") as evidence that a blinded review was the standard set by the profession. The

[5] The district court also granted LabCorp's motions to exclude Dr. Rosenthal's opinions on causation and inadequate "continuous quality improvement" efforts. However, the district court's ruling on Dr. Rosenthal's standard of care testimony is the only evidentiary ruling before us in this appeal. (The Adamses had a second expert witness testify as to causation. Dr. George Kemp testified that the cytotechnologists' failure to identify abnormal cells on Ms. Adams's slide delayed the diagnosis of her cancer by several years and thus prevented her from receiving treatment before her precancerous condition became cancerous. So it appears from the record—though we express no opinion on the matter—that Dr. Rosenthal's causation testimony was not the only causation evidence for the Adamses' claim based on negligence by LabCorp's cytotechnologists.)

[6] There are many forms of blinded review. For purposes of this case, the general defining feature of a blinded review that distinguishes it from Dr. Rosenthal's approach is that, in a blinded review, the person reviewing a Pap smear slide does not know (1) the identity of the person to whom any particular slide belongs, or (2) the ultimate outcome for that person (i.e., whether the person has been diagnosed with cervical cancer).

district court was troubled by the risk of bias in Dr. Rosenthal's assessment, based on the general risk of review bias in non-blinded reviews,[7] as well as Dr. Rosenthal's deposition statements about her "philosophical bent" toward patients later diagnosed with cancer. Finally, the district court observed that Dr. Rosenthal's methodology did not adequately simulate a cytotechnologist's working conditions and circumstances, and that her role as a pathologist is "materially different in function and scope" from that of a cytotechnologist.

After Dr. Rosenthal's opinion on the standard of care was excluded, the district court granted LabCorp's motion for summary judgment.

II.

We review for abuse of discretion a district court's evidentiary ruling under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141–42 (1997). We defer to the district court unless its ruling was "manifestly erroneous." *Tampa Bay Water v. HDR Eng'g, Inc.*, 731 F.3d 1171, 1183 (11th Cir. 2013) (quoting *Joiner*, 522 U.S. at 142). The deference we show includes giving the court "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Even where a

[7] In her deposition, Dr. Rosenthal defined "review bias" as a form of hindsight bias. She explained that, "[a]ny time you go to look at another case somebody else has looked at and rendered a diagnosis, you're biased by what they called it, and you're also biased if you have any additional information."

ruling excluding expert testimony is "outcome determinative" and the basis for a grant of summary judgment, our review is not more searching than it would otherwise be. *Joiner*, 522 U.S. at 142–43.

III.

The Adamses contend that the district court abused its discretion in excluding Dr. Rosenthal's testimony.

In *Daubert*, the Supreme Court explained that trial courts must act as "gatekeepers" tasked with screening out "speculative, unreliable expert testimony." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010) (citing *Daubert*, 509 U.S. at 597). In that role, trial courts may consider a non-exhaustive list of factors including (1) whether the expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential error rate of the technique; and (4) whether the technique is generally accepted in the scientific community. *Id.* Later, in *Kumho*, the Court explained that the gatekeeping function governs all expert testimony based on "scientific technical, or other specialized knowledge," not just scientific testimony. 526 U.S. at 147–49 (quoting Fed. R. Evid. 702). The Court also stressed that the factors identified in *Daubert* "do *not* constitute a definitive checklist or test." *Id.* at 150 (internal quotation marks omitted). While those factors may help in assessing the reliability of scientific or experience-based expert testimony, the district court's

"gatekeeping inquiry must be tied to the facts of a particular case." *Id.* (internal quotation marks omitted). Furthermore, *Kumho* emphasized that the goal of gatekeeping is to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

Federal Rule of Evidence 702, as amended in response to *Daubert* and *Kumho*, provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

We have distilled from *Daubert*, *Kumho*, and Rule 702 these three requirements: First, "the expert must be qualified to testify competently regarding the matter he or she intends to address"; second, the expert's "methodology . . . must be reliable as determined by a *Daubert* inquiry"; and third, the expert's "testimony must assist

the trier of fact through the application of expertise to understand the evidence or determine a fact in issue." *Kilpatrick*, 613 F.3d at 1335.[8]

The district court excluded Dr. Rosenthal's testimony based on its conclusion that her methodology was unreliable.[9] The court gave four grounds for its decision. We address each in turn.

A.

The district court determined that "Dr. Rosenthal's methodology . . . is an *ipse dixit* assessment that is devoid of any methodology that would allow another expert to challenge it in any objective sense." *Adams v. Lab. Corp. of Am.*, No. 1:10-CV-3309-WSD, 2012 WL 370262, at *15 (N.D. Ga. Feb. 3, 2012). The court

[8] In federal diversity actions, state law (Georgia law in the present case) governs substantive issues and federal law governs procedural issues. *McDowell v. Brown*, 392 F.3d 1283, 1294 (11th Cir. 2004). The district court did not exclude Dr. Rosenthal's testimony based on substantive Georgia law; it relied on its federal Rule 702 analysis. *See infra* note 9. So there is no substantive state law issue presented on appeal.

[9] The district court did not find that Dr. Rosenthal's testimony failed to meet the first and third requirements of Rule 702 (qualification to testify and helpfulness to the jury). The court noted that LabCorp "does not dispute [Dr. Rosenthal's] qualifications under Georgia law or *Daubert* to offer an opinion on the standard of care." *Adams v. Lab. Corp. of Am.*, No. 1:10-CV-3309-WSD, 2012 WL 370262, at *10 (N.D. Ga. Feb. 3, 2012). However, certain language in the district court's opinion suggests that the court may have believed that Dr. Rosenthal was not qualified to testify about cytotechnologists' standard of care, given that her role as a cytopathologist is "materially different in function and scope" from that of a cytotechnologist. *Id.* at *16. To the extent that the district court found that Dr. Rosenthal was not qualified to offer testimony on the standard of care and excluded her testimony on that ground, it was an abuse of discretion to do so. Dr. Rosenthal has stellar qualifications as a cytopathologist, is Board-certified in cytopathology, has trained cytotechnologists for over forty years, and was on the task force that developed the terminology they use. *See supra* at 3–4. She could hardly have been more qualified. *Cf. McDowell*, 392 F.3d at 1296 ("A physician's area of expertise necessarily encompasses the standard of care applicable to nurses.").

criticized her further for "not engag[ing] in a peer-reviewable evaluation because her opinion was reached without the implementation of any objective standards or controls." *Id.*

The district court's determination was a "manifestly erroneous" conclusion. *Tampa Bay Water*, 731 F.3d at 1183. Dr. Rosenthal did not make an *ipse dixit* assessment. Her opinion "was based on a widely accepted methodology and grounded in the available physical evidence." *United Fire & Cas. Co. v. Whirlpool Corp.*, 704 F.3d 1338, 1342 (11th Cir. 2013). She personally reviewed the available physical evidence, which consisted of Ms. Adams's Pap smear slides that had been sent to LabCorp for the Pap tests. Dr. Rosenthal did so using the same standard microscope as LabCorp's cytotechnologists, scanning each slide in the same general manner as its cytotechnologists do.[10] She later photographed Ms. Adams's slides and used those photographs in her deposition testimony, marking the areas in each picture where she had identified an abnormality.

Dr. Rosenthal used a well-established classification system to assess the cells: the same Bethesda System that LabCorp's cytotechnologists use. In her deposition testimony she went picture-by-picture, pointing to specific places in each one where Ms. Adams's cells showed abnormalities and classifying those

[10] The only arguably appreciable differences between Dr. Rosenthal's method and the review method for LabCorp's cytotechnologists is that Dr. Rosenthal (1) already knew that the patient whose slides she was reviewing had developed cancer and (2) reviewed slides from just one patient. Those differences relate to the lack of blinded review, which we address later. *See infra* Sections III.C–D.

abnormalities using the same Bethesda classification system that is used by LabCorp's cytotechnologists and nearly every other professional in the field of cytopathology. And the Bethesda Atlas, which is maintained by the ASC, provides numerous examples of each abnormality that Dr. Rosenthal identified, including "classic examples" of abnormal cells as well as "borderline" cells. As Dr. Rosenthal explained in her deposition, the images in the Atlas could be used to assess whether her opinion was in step with the established standards in the field. The fact that Dr. Rosenthal applied an established diagnostic system in which she was well versed contributed to the reliability of her methodology. *See, e.g.*, *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 246–47, 251 (5th Cir. 2002) (reversing the district court's exclusion of a medical expert's testimony after concluding that the expert's methodology was sufficiently reliable, in part because he formed his opinion "based on generally accepted diagnostic principles" that he applied in his personal examination of the plaintiff).

In addition to the Bethesda System, Dr. Rosenthal used her extensive experience in the fields of cytopathology and cytotechnology to assess whether LabCorp's employees' failure to identify those cells fell below the standard of care. She served on the task force that developed the Bethesda System terminology, the same diagnostic system that LabCorp's cytotechnologists use and that she used to review their work. Dr. Rosenthal reviews an average of 150 Pap

smear slides every six weeks as part of her duties at Johns Hopkins, and she has trained cytotechnologists for more than forty years. That experience, as well as her knowledge of the risk of review bias,[11] made her well aware of the conditions and limitations of the LabCorp cytotechnologists' review and of her own review of their work.[12] As she explained, the criterion she applied during her review was "what would I expect a brand new cytotech student the next day after she graduates or he graduates to do with this case if they saw it." Dr. Rosenthal's application of her extensive, relevant experience contributed to the reliability of her methodology. *See, e.g.*, *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 982 (6th Cir. 2004) (holding that the district court abused its discretion in excluding a doctor's standard-of-care testimony that was "supported by extensive relevant experience"); *see also Kilpatrick*, 613 F.3d at 1336 ("[T]here are instances in which a district court may determine the reliability prong under

[11] *See supra* note 7 (defining review bias).

[12] During Dr. Rosenthal's deposition, LabCorp's counsel asked her about the possibility that knowing Ms. Adams's diagnosis had biased her review of the slides. Dr. Rosenthal began her answer by pointing out that she was aware that many false negatives were not the fault of the cytotechnologist and referred to a 1989 study in which she participated that showed that fact. She then said that in conducting her non-blinded review of Ms. Adams's slides she had considered the position that the cytotechnologists had been in when examining those slides. She explained that:

> [W]hen I'm sitting down and I'm going to review, I don't always expect – even if I have a lawyer sitting along side [sic] of me – I don't expect every time to find abnormal cells, because I know the frailties of the Pap test, both from a sampling device and from the ability to distinguish between benign and reactive. So that bias, I think it depends upon what your vent [bent?] is when you're sitting down reviewing any case.

Daubert based primarily upon an expert's experience and general knowledge in the field."). It is difficult to imagine how Dr. Rosenthal's experience could have been more extensive and relevant or contributed more to the reliability of the methodology she used.

Dr. Rosenthal formed her opinion by using reliable tools, applying an established body of medical knowledge, and drawing on her extensive experience in the field.[13] That is not an *ipse dixit* assessment. The best evidence that it is not comes—indirectly—from LabCorp's own expert witness, Dr. Seena Aisner. She used the *same* general non-blinded approach as Dr. Rosenthal. Dr. Aisner received Ms. Adams's slides from LabCorp and then, without doing a blinded review,

[13] Our concurring colleague questions our approach because we review Dr. Rosenthal's "methodology" when, in his view, her testimony was based "only on the application of professional judgment, not 'methodology.'" He asserts that "there is no methodology" where the expert's opinion involves only "the *application* of [medical] knowledge." In using the terminology of methodology we are referring to the manner in which Dr. Rosenthal reviewed the slides, applied her medical knowledge and experience, including her familiarity with the Bethesda Atlas, and formed her opinion. Whether her approach is called a "methodology" or simply "application of professional judgment" does not matter. Whatever the terminology, the approach is subject to a reliability inquiry. Our case law is clear that even in cases where the reliability determination turns primarily on an expert's experience, "the district court must still determine the reliability of the opinion, not merely the qualifications of the expert who offers it." *Kilpatrick*, 613 F.3d at 1336. So courts should still consider whether the manner (some might say methodology) of applying medical knowledge is itself reliable. *See, e.g.*, *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 762 (3d Cir. 1994) (examining whether "evaluation of the patient's medical records . . . is a reliable method of concluding that a patient is ill even in the absence of a physical examination"). If, for instance, Dr. Rosenthal had viewed slides that were different from the ones that LabCorp's cytotechnologists screened (e.g., slides that had been taken later than the ones at issue), then her method probably would not be reliable under Rule 702. *See id.* As the concurring opinion points out, the application of *Daubert* is necessarily flexible and case specific. Whatever the terminology, we have inquired into the reliability of Dr. Rosenthal's approach and concluded that the district court abused its discretion in finding that approach was not reliable.

evaluated those slides without mixing in slides from any other patients. She then gave her own opinion about each slide, and in her deposition explained why she disagreed with Dr. Rosenthal's opinion. That squarely contradicts the district court's assertion that Dr. Rosenthal's methodology did not "allow another expert to challenge it in any objective sense" and was not "a peer-reviewable evaluation." *Adams*, 2012 WL 370262, at *15. The methodology not only allowed Dr. Aisner to challenge Dr. Rosenthal's opinion, she did challenge it.

B.

The district court also concluded that Dr. Rosenthal's methodology did not "satisfy the generally accepted standards in the area of pathology or cytotechnology." *Adams*, 2012 WL 370262, at *15. Specifically, it faulted her for failing to conduct "a blinded review[,] which is the standard set by the profession in which Dr. Rosenthal practices." *Id.* The court decided that a blinded review was the standard set by the profession based on the litigation guidelines created by the CAP and ASC. *Id.* at *12–15. That was an error of law because *Daubert* and *Kumho* do not allow courts to delegate to potential defendants decisions about when and how they may be held civilly liable for their mistakes. And an error of law is necessarily an abuse of discretion. *See City of Tuscaloosa v. Harcros Chemicals, Inc.*, 158 F.3d 548, 556 (11th Cir. 1998).

As an initial matter, it is important to put these guidelines in context. Both sets of them focus not on 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 and similar professionals. In the words of the guidelines, they are to be used in assessing Pap smear slides "in conjunction with litigation or potential litigation."[14] They are not objective, scientific findings; they are not guidelines followed by laboratories to screen for pre-cancerous or cancerous cells; they are policy proposals to limit how the courts can find the members of the organizations liable for professional negligence when they are sued.[15]

As far as we are aware, this is 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.[16] The members of the CAP and ASC have a substantial interest in making it more difficult for plaintiffs

[14] The CAP's guidelines are titled "Guidelines for the Review of Pap Tests in the Context of Litigation or Potential Litigation," while the ASC's guidelines are titled "Guidelines for Review of GYN Cytology Samples in the Context of Litigation or Potential Litigation."

[15] The CAP puts the headline "Policy" above its guidelines. And both sets of guidelines state that they are proposals for establishing a method of reviewing Pap test slides "that is fair to both the patient and the laboratory." An assessment of what is "fair" is obviously a value judgment, not a scientific finding or standard.

[16] At oral argument, we asked counsel for LabCorp if she was aware of any similar guidelines from any other private organization or industry group. She replied that she was not.

to sue based on alleged negligence in their Pap smear screening,[17] and their guidelines do just that.

Both sets of guidelines condemn the practice of allowing plaintiffs to use expert opinions, like Dr. Rosenthal's, that are formed based on a review of the slides in which the expert already knows the patient has been diagnosed with cancer. The ASC says that: "Focused review or review with knowledge of subsequent development of carcinoma inevitably biases the objectivity of the review against the laboratory and does not reflect standard practice." And the CAP says that: "Focussed [sic] review, or review with knowledge of subsequent development of carcinoma, biases the objectivity of the review." The CAP goes on to declare that: "Unless the review is blinded, it cannot establish deviation from the standard of practice." That, of course, is a decision to be made by courts, not by self-interested associations.

To address review bias, both sets of guidelines propose that plaintiffs have multiple reviewers conduct a "blind" review in which (a) the plaintiff's slides are mixed in with other normal and abnormal slides, (b) those slides are sent to multiple reviewers who do not know which slides are the plaintiff's, and (c) those reviewers offer their opinion on which slides are normal and which are abnormal.

[17] Both organizations reveal their motivation to reduce litigation when they propose, as one of their guidelines, that "parties should also strongly consider mediation or non-binding arbitration by a panel of individuals trained and having experience in cytopathology before proceeding with civil litigation relating to a Pap test."

The guidelines insist that there can be no breach of the duty of care "unless there is a consistent finding by the reviewers that the laboratory failed to identify clinically significant abnormalities." The guidelines seek to skew the evidentiary rules in civil litigation against plaintiffs in at least two ways.[18]

The first way is by imposing a requirement on expert testimony for a plaintiff that, as far as this Court is aware, no court has ever imposed on standard-of-care testimony in professional negligence cases: that an expert witness must eliminate any potential "review bias" in her opinion. Bias in an expert witness's testimony is usually a credibility issue for the jury. *See United States v. Abonce-Barrera*, 257 F.3d 959, 965 (9th Cir. 2001); *DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000). But both sets of guidelines treat the mere risk of review bias as intolerable. They do not specify the frequency or degree to which review bias actually affects reviewers' judgments. Nor do they cite any empirical evidence supporting their assertion that knowing the outcome "inevitably biases" the reviewer.[19] Yet they insist that a court should exclude expert testimony unless

[18] The district court did note that it was "not hold[ing] that a blinded review conducted pursuant to the College of American Pathologists and American Society of Cytopathology litigation slide review guidelines is the only methodology that would allow an expert to offer an opinion on the standard of care for a cytotechnologist in reviewing Pap smear slides." *Adams*, 2012 WL 370262, at *17 n.11. The court did not, however, specify what form of blinded review short of the kind specified in the CAP and ASC guidelines might suffice. In any event, it is apparent that the CAP and ASC guidelines are the lynchpin for the court's ruling. They are the sole support offered for the court's conclusion that any form of non-blinded review is unreliable.

[19] Both sets of guidelines assert that Pap tests performed on patients have an "irreducible false negative rate" of about five percent. But that does not support the claim that non-blinded

the expert has eliminated entirely the possibility of any review bias. That would be a radical reworking of Rule 702, which requires courts to determine that the expert's method is reliable, not that it is free of any possibility of bias.

The second way the guidelines would skew the evidentiary rules against plaintiffs is by imposing a one-sided standard for reliability. Both sets of guidelines require a blinded review to establish a breach of the standard of care, but neither one requires defense experts to base their opinions on a blinded review. (Maybe that is why LabCorp's expert, Dr. Aisner, did not conduct a blinded review when she evaluated Ms. Adams's slides.) For example, the CAP's guidelines say, point blank, that "[o]ne asserting a violation of the standard of care 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." The "one asserting a violation of the standard of care" is, of course, the plaintiff. The guidelines impose no similar obligation on expert witnesses for the defense. And the ASC's guidelines condemn non-blinded review because it "biases the objectivity of the review against the laboratory," but express no

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reviews are hopelessly subjective and biased. The guidelines themselves reveal that the irreducible error rate in initial Pap screening tests is due to "[m]any factors," and name "sampling problems with specimen collection" as one of them. Any sampling problems in the collection of the cells could not have affected Dr. Rosenthal's methodology or her opinion because she examined all of the slides examined by the cytotechnologists, not a sample of them. The sampling was done before she or the cytotechnologists saw any of the slides. The question is what happened after the cells were collected and placed on the slides.

concern about non-blinded review biasing the assessment of defense experts against plaintiffs. Clearly, the purpose of the guidelines is to raise the bar only on the plaintiffs' side of the courtroom.

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." *Adams*, 2012 WL 370262, at *14 (emphasis added). But neither *Daubert* nor *Kumho* permits a scientific or medical community to define a "litigation standard" that applies when its members are sued.

Daubert did acknowledge that, where expert testimony is based on a scientific technique or theory, courts may consider "the particular degree of acceptance" it has in "a relevant scientific community" as an indicator of its reliability. 509 U.S. at 594 (internal quotation marks omitted). But the "acceptance" to which *Daubert* refers is the acceptance that the technique or theory has in the community's own field of practice when the science is being applied outside of the litigation context, not the scientific community's opinion about the standard or type of proof that should be required in litigation. As the Supreme Court later acknowledged, "there are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory." *Id.* at 596–97. One of those differences is that the scientific community's search for truth is

"subject to perpetual revision" and not driven by the self-interest of parties in litigation. *Id.* at 597.[20]

With their guidelines for litigation, the CAP and ASC moved away from disinterested scientific inquiry and into litigation policy to serve their members' own interests. However much the members of those associations may accept and even applaud the move, it is not scientific acceptance, which is what *Daubert* involves. Nor is litigation policy "the practice of an expert in the relevant field," as *Kumho* thought of it. *See Kumho*, 526 U.S. at 152 (stating that the district court's gatekeeper function is meant to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). The district court's ruling runs afoul of those two decisions, which do not permit delegating to industry groups the gatekeeping duties of the courts.

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. For example,

[20] We do not mean to suggest that *Daubert*'s acceptance factor cannot apply to scientific techniques that are primarily applied in law enforcement and the courtroom, such as fingerprint analysis and other forensic disciplines. *See, e.g.*, *United States v. Abreu*, 406 F.3d 1304, 1307 (11th Cir. 2005); *see generally Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 n.5 (9th Cir. 1995). Instead, we mean that when analyzing the "general acceptance" factor from *Daubert*, it matters whether an industry group whose expertise lies outside the litigation context is advocating a policy position to benefit its members in litigation.

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 define the meaning of "deliberate indifference" or the requirements for admission of evidence in custodial litigation? They can't because courts do not allow interested groups to set evidentiary or other litigation standards.

C.

The district court also determined that, even apart from the guidelines, Dr. Rosenthal's methodology was unreliable because "review bias i[s] inherent" in a non-blinded review, and she admitted in her deposition that she had a "philosophical 'bent toward a plaintiff who has developed cervical cancer.'" *Adams*, 2012 WL 370262, at *15. In doing that, the district court supplanted the jury's factfinding role.

We have repeatedly stressed *Daubert*'s teaching that the gatekeeping function under Rule 702 "is not intended to supplant the adversary system or the role of the jury: 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking *shaky but admissible evidence*.'" *United States v. Alabama*

Power Co., 730 F.3d 1278, 1282 (11th Cir. 2013) (emphasis added) (quoting *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1311–12 (11th Cir. 1999)). That is the case here.

At most, LabCorp established that there is an unspecified level of risk that Dr. Rosenthal's assessment might have been biased, and that she had not sought to exclude the possibility of bias by conducting a blinded review. *See supra* note 19 and accompanying text. The risk of bias would mean, at most, that Dr. Rosenthal's testimony is to some extent "shaky," and shakiness goes to the weight of her testimony, not its admissibility. *See Ala. Power Co.*, 730 F.3d at 1282; *see also Rosenfeld v. Oceania Cruises, Inc.*, 654 F.3d 1190, 1193 (11th Cir. 2011) ("[I]n most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility." (internal quotation marks omitted)). All of the bias concerns that the court raised could have been presented to and considered by the jury. LabCorp could cross-examine Dr. Rosenthal to bring out any bias she had and to expose the risk of bias inherent in the methodology she used. LabCorp's attorney did question Dr. Rosenthal on the subject at great length during her deposition, asking her about review bias, the virtue of blinded reviews, and her philosophical bent in favor of plaintiffs with cancer. She could have done the same thing before the jury. Hindsight bias is a common-sense concept—everyone knows that "hindsight is

20/20." And common-sense concepts are especially appropriate for consideration by a jury. *See Stollings v. Ryobi Technologies, Inc.*, 725 F.3d 753, 766 (7th Cir. 2013) ("The judge should permit the jury to weigh the strength of the expert's conclusions, provided such shortcomings are within the realm of a lay juror's understanding."). Whether and, if so, the extent to which an expert's philosophical bent biases her review is a credibility determination that has always been within the province of the jury. *See DiCarlo*, 211 F.3d at 468. The same is true of an outcome-knowledge bent. The asserted problems with Dr. Rosenthal's testimony could be addressed through the conventional adversarial means and assessed by the jury. Absent some other basis for summary judgment, they should be.

D.

Finally, the district court faulted Dr. Rosenthal's methodology because her "approach did not account for the similar conditions and surrounding circumstances under which a cytotechnologist works and originally viewed the slides." *Adams*, 2012 WL 370262, at *15. The court noted that "[i]t is a fundamental principle under Georgia law that the standard of care in medical malpractice actions requires that expert opinions take into account 'similar conditions and like surrounding circumstances.'" *Id.* It then reasoned that Dr. Rosenthal's testimony was unreliable because she had not recreated the conditions and circumstances cytotechnologists face because she did not look at a large

number of slides without already knowing whether they contained cells that were abnormal. *Id.* at *15–16. Even assuming that Georgia law should apply in Rule 702 analysis, the district court's reasoning was manifestly erroneous.

First, the court overlooked Dr. Rosenthal's experience in training cytotechnologists and her deposition testimony explaining that when she reviews slides she does consider the conditions under which cytotechnologists conduct their review.[21] Second, Georgia courts have not interpreted their malpractice standard to require that expert witnesses "stand in the shoes of the defendant" as the district court says they must. *See, e.g.*, *Hankla v. Jackson*, 699 S.E.2d 610, 612–13 (Ga. Ct. App. 2010) (allowing an expert witness in a medical malpractice case to rely on her review of the plaintiff's medical records in testifying that the nurse midwife breached the standard of care). The district court's reasoning seemingly would bar all expert medical testimony unless the expert has somehow recreated the same conditions that the defendant was under. For example, if a plaintiff claimed that a defendant doctor prescribed her improper levels of medication, the expert could not just review the plaintiff's medical file to form his opinion. After all, the defendant doctor probably saw numerous patients that day and did so without the benefit of knowing what reaction that a given patient would have to a prescription. Under a standing-in-the-shoes requirement, a plaintiff's file

[21] *See supra* note 12 and accompanying text.

would have to be mixed in with numerous others and then sent to several doctors who would recommend prescription levels for all of the patients. The plaintiff would have a negligence claim only if those reviewers consistently recommended a different level of medication for the plaintiff. Rule 702 does not impose such a requirement.

Dr. Rosenthal was qualified to testify about cytotechnologists' standard of care, her methodology was reliable, and her testimony would assist the trier of fact. *Kilpatrick*, 513 F.3d at 1335. Accordingly, the district court abused its discretion in excluding her testimony.

IV.

For the foregoing reasons, we REVERSE the district court's ruling excluding Dr. Rosenthal's opinion on the standard of care for cytotechnologists, VACATE the district court's grant of summary judgment to LabCorp, and REMAND for further proceedings consistent with this opinion.

GARZA, Circuit Judge, specially concurring:

I concur in the judgment and in the majority's conclusion that the district court abused its discretion in excluding Dr. Rosenthal's testimony. I also agree with the majority's reasoning with the exception of its discussion of Dr. Rosenthal's "methodology," primarily in Part III.A. In my view, Dr. Rosenthal's testimony on the standard of care and its alleged breach in this case is admissible because her qualifications and experience are sufficient. Under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this case does not implicate any "methodology." Rather, the reliability of Dr. Rosenthal's testimony on the standard of care and its alleged breach depends only upon her knowledge of the abnormalities that a Laboratory Corporation of America ("LabCorp") cytotechnologist should be capable of detecting in Pap smear slides.

A.

Implicit in the majority's analysis is that the admissibility of Dr. Rosenthal's opinion hinges on the reliability of her "methodology." *Ante* at 9. Although that methodology is never precisely defined, the majority mentions Dr. Rosenthal's "personally review[ing] the available physical evidence, which consisted of Ms. Adams's Pap smear slides," "using the same standard microscope as LabCorp's cytotechnologists," "scanning each slide in the same general manner as its

cytotechnologists do," and "photograph[ing] Ms. Adams's slides and us[ing] those photographs in her deposition testimony." *Id.* at 10. In the majority's view, moreover, the fact that Dr. Rosenthal "applied an established diagnostic system in which she was well versed," *id.* at 11, and "appli[ed] . . . her extensive, relevant experience contributed to the reliability of her methodology," *id.* at 12.

In my view, the majority's attention to "methodology" misses the mark. The majority fails to focus on the record evidence that illuminates the exact dispute before us—namely, the specifics of a cytotechnologist's task and the manner in which Dr. Rosenthal formed her opinion about Ms. Adams's slides.

Cytotechnologists are responsible for screening Pap smear slides for signs of disease and malignancy. A single slide can contain thousands of cells, and cytotechnologists must flag for further review by a pathologist any cells that might be cancerous or precancerous. This determination is guided by the Bethesda System, an atlas of images containing various "classic examples" of cytomorphologic features.[1] In Dr. Rosenthal's words, properly trained cytotechnologists will "know what benign looks like" when they "decide whether or not they're going to send [the slide] on to the pathologist." Without constant practice in this "qualitative, subjective skill," even Dr. Rosenthal requires "a few days . . . to 'get [her] eye back.'" A cytotechnologist's task, then, involves not a

[1] As the Adamses note, the Bethesda System's atlas containing its images and classifications can be found online at http://nih.techriver.net/index.php.

"methodology," but judgment—refined and disciplined through training, practice, and knowledge of cytomorphologic features so that one is capable of detecting abnormalities.

This professional judgment underlies Dr. Rosenthal's testimony about a cytotechnologist's standard of care and the LabCorp cytotechnologists' alleged breach of that standard. In her deposition, Dr. Rosenthal explained the "standard of care" as "what a recent graduate of a cytotechnology training program would be able to detect under normal screening conditions on a particular slide as an abnormality"—a domain of knowledge with which she is intimately familiar, having trained cytotechnologists for forty years. As for the alleged breach of the standard of care, Dr. Rosenthal's expert report concluded that on numerous occasions, LabCorp cytotechnologists "misinterpreted" Ms. Adams's Pap smear slides and that these errors accordingly "fell below the standard of care for a cytotechnologist."[2] These opinions on the alleged breach followed from her visual observation of Ms. Adams's slides and were "based on over 40 years of professional experience at two major medical centers in which [her] career was

[2] For instance, Dr. Rosenthal's report claimed: "The March 20, 2008 Pap test was misinterpreted by cytotechnologists Robert Allison and Greg McDaniel, as showing 'NILM [negative for intraepithelial lesion and malignancy] with squamous component cells present'. This error in interpretation fell below the standard of care for a cytotechnologist." Dr. Rosenthal's affidavit elaborates on her opinion as to the correct assessment of the March 20, 2008 test: "The test actually revealed HSIL [high-grade squamous intraepithelial lesion] with endocervical component cells present," where HSIL is a "high grade cervical cancer precursor condition."

devoted to cytologic interpretation."[3] In addition to her experience, Dr. Rosenthal relied on the Bethesda System classifications, which, again, are the same as those used by the cytotechnologists in this case.

Both the cytotechnologist's task and Dr. Rosenthal's review involve only the application of professional judgment, not "methodology."[4] The majority, however, erroneously conflates scientific knowledge with scientific "methodology." To be sure, both LabCorp cytotechnologists and Dr. Rosenthal applied knowledge *derived* through a scientific methodology—*i.e.*, knowledge of the various cell classifications catalogued in the Bethesda System, whose validity is not in

[3] As the majority explains, Dr. Rosenthal has been a pathology professor since 1995, served on the task force that developed the Bethesda System used by cytotechnologists for reporting Pap smear results, and has over forty years of experience in training cytotechnologists. *Ante* at 3–4.

[4] The majority asserts that "[w]hether [Dr. Rosenthal's] approach is called a 'methodology' or simply 'application of professional judgment' does not matter." *Ante* at 13 n.13. But words *do* matter to trial courts tasked with ensuring the reliability of expert testimony under Rule 702 and *Daubert*. Here, Dr. Rosenthal's application of her knowledge of the standard of care and identification of an alleged breach do not implicate a methodology warranting independent scrutiny. By contrast, in *Daubert* and *Kumho Tire*, the Supreme Court assessed the methodologies of experts who sought to testify, respectively, that a particular drug caused birth defects and that a tire's manufacturing or design defect caused its failure. *See Daubert*, 509 U.S. at 593 ("Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry."); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153–54 (1999) ("[T]he specific issue before the court was not the reasonableness *in general* of a tire expert's use of a visual and tactile inspection to determine whether overdeflection had caused the tire's tread to separate from its steel-belted carcass. Rather, it was the reasonableness of using such an approach, along with [the expert's] particular method of analyzing the data thereby obtained, to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant*.").

dispute.[5] But in the *application* of this knowledge, there is no methodology; the observer merely views a slide and forms her judgment based on her knowledge.

B.

Because the admissibility of Dr. Rosenthal's testimony hinges on the reliability of her knowledge of a cytotechnologist's standard of care rather than the reliability of any "methodology," her competence renders her testimony admissible under *McDowell v. Brown*, 392 F.3d 1283 (11th Cir. 2004).

In *McDowell*, this Circuit held that the competency of a standard-of-care expert satisfies the demands of Rule 702 and *Daubert*. In that case, McDowell brought a medical negligence suit under Georgia law against Wexford Health Sources, which provided medical services in the jail in which he was detained. *Id.* at 1286–87. McDowell alleged that despite his symptoms of severe pain, Wexford's nurse negligently failed to arrange for his timely transport to a nearby hospital for treatment, and that this delay proximately caused his partial paraplegia. *Id.* To support his claim, McDowell sought to have three doctors testify that Wexford's nurse breached the standard of care applicable to nurses. The district court, however, excluded his experts' testimony on the basis that they were

[5] The majority, notably, does not claim that the Bethesda System itself is a "methodology," but only that Dr. Rosenthal's use of that "well-established classification system" "contributed to the reliability of her methodology." *Ante* at 10–11.

"unqualified to render an opinion as to the standard of care applicable to nurses." *Id.* at 1296.

On appeal, this Court reversed the district court's ruling, basing its determination on the experts' competency, without mention of any "methodology." The panel began by explaining that the admissibility of standard-of-care expert testimony hinges on both state substantive law and federal procedural law: "[I]f a witness is deemed competent to testify to the substantive issue in the case [under state law], such as the standard of care, his or her testimony should *then* be screened by Rule 702 to determine if it is otherwise admissible expert testimony." *Id.* at 1295 (quoting *Legg v. Chopra*, 286 F.3d 286, 292 (6th Cir. 2002) (emphasis added)). Next, the panel explained that under Georgia law, a standard-of-care expert in a medical malpractice case must possess "knowledge of the standard of care applicable to the defendant-professional as to at least one of the matters on which the plaintiff's malpractice claim is based." *Id.* at 1296 (citation omitted). The panel reasoned that because "[a] physician's area of expertise necessarily encompasses the standard of care applicable to nurses," *id.*, "the experts [were] competent to render opinions as to the applicable standard of care for Wexford's nurses," *id.* at 1297.

The panel ultimately concluded that "the district court erred in excluding the experts' testimony as to the applicable standard of care." *Id.* at 1301. To be sure,

the panel did not expressly assess the standard-of-care testimony under either Rule 702 or *Daubert*.[6] However, the panel's earlier conclusion that these federal evidentiary rules govern the standard-of-care expert testimony in addition to state substantive law, *id.* at 1295, can only mean that the doctors' competency under Georgia law was also sufficient to satisfy both Rule 702 and *Daubert*.[7]

McDowell governs this case. Here, like the doctors in *McDowell*, Dr. Rosenthal was amply competent to testify about the alleged breach of the standard of care in light of her "knowledge of the standard of care applicable to the defendant-professional." *Id.* at 1296. Indeed, the parties do not dispute her competency, *ante* at 9 n.9, and the majority acknowledges Dr. Rosenthal's "extensive" qualifications, *id.* at 3. Moreover, neither *McDowell* nor this case implicates a "methodology"; rather, both cases involve the expert's application of professional knowledge to certain facts. Here, those facts were contained on Ms. Adams's Pap smear slides; in *McDowell*, they took the form of McDowell's acute symptoms. *McDowell*, 392 F.3d at 1286–87. So long as Dr. Rosenthal has applied

[6] By contrast, the *McDowell* panel explicitly applied Rule 702 and *Daubert* in concluding that the district court did not abuse its discretion in excluding expert testimony about causation, since the experts offered little support for their belief that McDowell's treatment delay caused his injury. *McDowell*, 392 F.3d at 1297–1301.

[7] For this reason, the majority incorrectly distinguishes *McDowell* on the grounds that "there is no substantive state law issue presented on appeal." *Ante* at 9 n.8. *McDowell* is the leading authority in this Circuit on the admissibility of medical malpractice standard-of-care expert testimony under *federal* procedural law, and stands for the proposition that such testimony is admissible under Rule 702 and *Daubert* so long as the expert is competent under state law.

medical or scientific knowledge in evaluating the actions or omissions of a cytotechnologist, her opinion is reliable.[8]

Accordingly, under *McDowell*, Dr. Rosenthal's opinion about the alleged breach of the cytotechnologist's standard of care is reliable and admissible.

C.

McDowell's recognition that standard-of-care expert testimony generally originates in professional judgment accords with this Circuit's case law on *Daubert* and with the decisions of several other circuits.

Experts testifying on the breach of a standard of care opine on the content of that standard and whether a party's behavior deviated from it. When such opinions are empirical, professional judgments, they are based on "reliable principles and methods" so long as they are derived from the expert's competency and qualifications. Fed. R. Evid. 702(c); *see also Palandjian v. Foster*, 842 N.E.2d 916, 923 & n.12 (Mass. 2006). Such testimony generally does not require devising new analyses to explain factual phenomena—an inquiry for which Rule 702 and *Daubert*'s concern with "methodology" is quintessentially important.[9] Nor must such experts precisely replicate a litigant's circumstances before they may opine on an alleged breach of the standard of care under those circumstances; hence, the

[8] Of course, once admitted, Dr. Rosenthal's testimony would be subjected to the rigors of cross-examination. *See ante* 21–22.
[9] *See supra* note 4.

majority correctly rejects LabCorp's contention that Dr. Rosenthal must "stand in the shoes" of actual cytotechnologists. *Ante* at 24–25. To be sure, the professional knowledge underlying testimony about the breach of a standard of care may have scientific bases—as in Dr. Rosenthal's case here, and in the case of the doctors in *McDowell*.[10] But as explained above, the application of scientific knowledge does not necessarily implicate a "methodology."

McDowell's attention to competency rather than methodology accords with this Circuit's flexible, context-sensitive application of *Daubert*. We recognize that "there are instances in which a district court may determine the reliability prong under *Daubert* based primarily upon an expert's *experience and general knowledge in the field*." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1336 (11th Cir. 2010) (citing *United States v. Brown*, 415 F.3d 1257 (11th Cir. 2005)) (emphasis added). We have further noted that "*Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case." *Brown*, 415 F.3d at 1267 (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999)). These principles find further support in the Advisory Committee Note's explanation that "the text of Rule 702 expressly contemplates that an expert may be qualified *on the basis of experience*." Fed. R. Evid. 702 advisory committee's

[10] In addition to scientific disciplines, an expert's knowledge subject to Rule 702 and *Daubert* can originate from other "technical" or "specialized" fields of inquiry. *See Kumho Tire*, 526 U.S. at 149. Here, however, Dr. Rosenthal's knowledge certainly has a scientific basis.

note (2000 Amendments) (emphasis added). The Note continues: "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Id.*; *see also Kumho Tire*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). As in *McDowell*, and as permitted by *Kilpatrick*, Dr. Rosenthal's "experience and general knowledge" are sufficient to satisfy Rule 702 and *Daubert*. *Kilpatrick*, 613 F.3d at 1336.

Similarly, several other courts of appeals applying Rule 702 and *Daubert* to standard-of-care expert testimony have determined that the testimony in question is admissible so long as the expert is competent or qualified. *See, e.g.*, *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn., P.C.*, 388 F.3d 976, 980–82 (6th Cir. 2004) (cardiac thoracic surgeon could testify about standard of care of pulmonologist on basis of "extensive relevant experience," *id.* at 982, and was not required to demonstrate familiarity with pulmonology literature or standards); *Sosna v. Binnington*, 321 F.3d 742, 745–46 (8th Cir. 2003) (concluding that internist was "competent," *id.* at 746, to testify about standard of care of surgeon, based on expertise and experience treating patients who underwent surgeries); *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405–409 (3d Cir.

2003) (concluding that two experts were competent to testify about standard of care based, respectively, on "experience," *id.* at 406, and "qualifications," *id.* at 409).

McDowell sets forth a sound general rule for screening expert testimony on the breach of a standard of care, and I would apply it here.

D.

By failing to delineate the boundaries of Dr. Rosenthal's "methodology," today's opinion neglects to explain when courts must depart from *McDowell* and undertake this additional assessment of "methodology."

The majority struggles to define Dr. Rosenthal's "methodology." In an apparent attempt, the majority observes that Dr. Rosenthal "personally reviewed the available physical evidence," "us[ed] the same standard microscope as LabCorp's cytotechnologists," "scan[ned] each slide in the same general manner as its cytotechnologists do," and later "photographed Ms. Adams's slides." *Ante* at 10. However, this *ad hoc* list of activities offers no principled explanation of where Dr. Rosenthal's "methodology" begins and ends. Adding to the confusion, the majority claims that Dr. Rosenthal need not "stand in the shoes of the defendant" by "recreat[ing] the conditions and circumstances cytotechnologists face"—that is, reviewing "a large number of slides without already knowing whether they contained cells that were abnormal." *Id.* at 23–24. While I agree that

replicating the exact circumstances of a cytotechnologist is wholly unnecessary, *supra* Part C, I can discern no analytical principles in the majority opinion for determining when an expert uses a methodology.

Because of the majority's inability to define Dr. Rosenthal's purported methodology, future courts have no guidance as to *when* scrutiny of methodology—an exception to *McDowell*—is required in the first place. In certain cases, I would agree that courts must validate the reliability of an expert's methodology.[11] For instance, to prove a breach of the standard of care, an expert might be called upon to establish the speed of a car at the moment of impact, or the temperature of a coffee when spilled.[12] But at least here, where the expert simply applies her professional judgment to the same facts that confronted the litigant, *McDowell* applies.[13]

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[11] Experts attempting to demonstrate causation often deploy methodologies to test whether a certain causal hypothesis has factual support. *See, e.g.*, *Kilpatrick*, 613 F.3d at 1336–43 (reviewing differential diagnosis methodology employed by expert testifying on causation and concluding that district court did not abuse discretion in excluding testimony for lack of reliable methodology); *see also Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1252–56 (11th Cir. 2010) (same); *see also supra* note 4 (discussing "methodology" at issue in *Daubert* and *Kumho Tire*).

[12] *See also Rosenfeld v. Oceania Cruises, Inc.*, 654 F.3d 1190, 1193 (11th Cir. 2011) (explaining that "[a] qualified expert who uses reliable testing methodology may testify as to the safety of a defendant's choice of flooring, determined by the surface's coefficient of friction"); *Lees v. Carthage College*, 714 F.3d 516, 524 (7th Cir. 2013) (noting that even if parties did not dispute expert's qualifications, assessment of reliability of expert's testimony about college's alleged breach of standard of care required further analysis of soundness of his "methodology").

[13] Moreover, as in *McDowell*, the conduct of the defendant is undisputed and requires no factual analysis by the expert: Here, the LabCorp cytotechnologists did not flag abnormalities for further review by a pathologist. For the purposes of this appeal, the only issue is whether this conduct breached the applicable standard of care.

* * *

As the majority correctly explains, Rule 702 and *Daubert* govern all expert testimony based on "scientific, technical, or other specialized knowledge." *Ante* at 7 (quoting *Kumho Tire*, 526 U.S. at 149). I thus agree that the gatekeeping inquiry under Rule 702 and *Daubert* applies to Dr. Rosenthal's testimony, which is certainly based on "scientific" knowledge.

At bottom, the majority and I disagree over the meaning of "methodology" and its role in the gatekeeping inquiry in this particular case.[14] In my view, neither the LabCorp cytotechnologists nor Dr. Rosenthal applied a methodology in assessing Ms. Adams's Pap smear slides; rather, they simply drew upon their knowledge in viewing those slides. Therefore, under *McDowell*, the reliability of Dr. Rosenthal's testimony on a cytotechnologist's standard of care and its alleged breach depends only on the reliability of her knowledge—*i.e.*, her competency. Accordingly, because no party disputes that Dr. Rosenthal is competent to testify

[14] The Supreme Court has not had occasion to clarify the meaning of "methodology," though the term has given rise to some disagreement among the Justices. In *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), the Court noted that "conclusions and methodology are not entirely distinct from one another," and that although "[t]rained experts commonly extrapolate from existing data," "nothing . . . requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Id.* at 146. Justice Stevens, in dissent, explained that the Court incorrectly blurred the line between methodology and conclusions, which he analogized to the conceptual difference between "means and ends." *Id.* at 155 (Stevens, J., dissenting). Justice Stevens claimed that the expert had reviewed the studies under a "'weight of the evidence' methodology," which was reliable enough to deem his testimony admissible and allow a jury to assess the soundness of his conclusions. *Id.* at 152–54 (Stevens, J., dissenting).

on the standard of care and its alleged breach, I would hold that the district court abused its discretion in excluding her testimony.