IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

CHRISTINA NICOLE ADAMS and CHRISTOPHER L. ADAMS, **Plaintiffs,** **v.** **LABORATORY CORPORATION OF AMERICA,** **Defendant.**	**1:10-cv-3309-WSD**

OPINION AND ORDER

This matter is before the Court on Christina Nicole Adams ("Adams") and Christopher L. Adams' ("Plaintiffs") Motion to Strike Declarations of Tiea L. Kesler [90], Laboratory Corporation of America's ("Defendant") Motion to Strike Plaintiffs' Re-Designation of Martha Bishop Pitman, M.D. and Pitman Affidavit [92], Plaintiffs' Request for Permission to File Supplemental Brief in Opposition to Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [96], Defendant's Motion for Leave to File Surreply in Further Support of Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [99], Defendant's Request to Take Judicial Notice [104], Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [74], Defendant's Motion for Summary Judgment [75],

and Plaintiffs' Motion to Exclude Testimony of Pathologist Regarding Standard of Care [73]

I. BACKGROUND

A. Overview

This is a negligence action against LabCorp for alleged misinterpretation of five Pap smear tests taken by Adams' physician from January 2006 through September 2008. In August 2009, Adams was diagnosed with cervical cancer. Plaintiffs allege that Defendant is liable for the negligence of its employees or agents who misinterpreted and reported inaccurate test results to Adams' physician. Plaintiffs argue that these alleged misinterpretations delayed the diagnosis of Adams' cancer, which permitted the cancer to metastasize. Plaintiffs seek recovery for injuries suffered by Adams and for Mr. Adams' loss of consortium.

B. Procedural background

On September 7, 2010, Plaintiffs filed their Complaint in the State Court of DeKalb County, Georgia. On October 17, 2010, Defendant removed the DeKalb County action to this Court. On November 15, 2010, the parties filed their Joint Preliminary Report and Discovery Plan (the "Joint Plan") [11]. On November 29, 2010, the Court conducted a telephone conference to discuss the schedule for

discovery, ordering that fact discovery be completed on or before March 21, 2011, and that expert discovery be completed on or before May 16, 2011 [14]. On December 10, 2010, the parties filed their Joint Detailed Discovery Plan[1] setting forth the specific plan for completing discovery. In the plan, the parties proposed different discovery schedules for the identification and deposition of experts. On December 14, 2010, the Court entered its order requiring the parties to identify experts and serve the expert reports no later than March 21, 2011, and that expert discovery be completed by May 16, 2011 [20].

On January 21, 2010, the parties moved to extend the discovery deadlines [27] due to inclement weather that had occurred in Atlanta. On January 27, 2011, the Court granted the motion [29], extending the discovery deadlines as follows:

- Complete depositions of fact witnesses by February 18, 2011;
- Complete depositions of treating physicians by March 18, 2011;
- Designate expert witnesses by March 25, 2011;
- Provide expert witness reports by April 8, 2011; and
- Complete depositions of expert witnesses by May 16, 2011.

("January 2011 Scheduling Order") [29]. The Court stated in the January 2011 Scheduling Order that "no further extensions will be granted" [29 at 2].

On March 7, 2011, Plaintiffs moved to amend their Complaint to add a claim for punitive damages.

[1] The Court in its November 29, 2010, telephone conference required the plan to be filed.

On March 24, 2011, Defendant filed its opposition to Plaintiffs' Motion to Amend [51], arguing that Plaintiffs had failed to show the requisite "good cause" for amending their Complaint after the amendment deadline set out in the Joint Plan.[2]

On March 24, 2011, the parties also advised the Court that, since the Joint Discovery Plan did not address rebuttal experts, they had agreed as follows:

> The parties agree that they will each disclose any rebuttal experts related to the claims currently at issue no later than *April 8, 2011*, and provide expert reports under Federal Rule of Civil Procedure 26(a)(2)(b) no later than *April 22, 2011*. These time frames are shorter than the time frames provided for rebuttal experts under the Federal Rules of Civil Procedure, but are intended to aid the parties in completing expert discovery by the May 16 deadline set by the Court.

[68-2].

On or about April 29, 2011, almost three weeks after the agreed-upon deadline to identify rebuttal experts, Plaintiffs, in a phone call or email, informally advised Defendant that they wanted to identify Drs. Martha Bishop Pitman and Mary Jane Minkin as experts. On May 2, 2011, Defendant moved to strike [68]

[2] The Joint Preliminary Report and Discovery Plan provided that "Amendments to the pleading submitted LATER THAN THIRTY (30) DAYS after the Joint Preliminary Report and Discovery Plan is filed . . . will not be accepted for filing, unless otherwise permitted by law [11 at 5]. Plaintiffs stated in the Joint Plan that they did not "anticipate amendments to the pleadings unless discovery reveals new information." Id.

this proposed new designation [68].[3] Defendant argued that the designations violated the agreed April 22, 2011, rebuttal expert designation date and that Drs. Pitman and Minkin otherwise were not proper rebuttal experts.

On May 7, 2011, Plaintiffs filed their response to Defendant's motion to exclude rebuttal experts and also moved to modify the January 2011 Scheduling Order to allow the testimony of the two rebuttal experts that Plaintiffs had identified. On May 7, 2011, Plaintiffs also formally identified Drs. Pitman and Minkin as rebuttal expert witnesses [71].

On June 7, 2011, Plaintiffs filed a motion to exclude the testimony of Dr. Seena Aisner, M.D., concerning the standard of care of a gynecologist [73].

On June 15, 2011, Defendant filed its Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [74] on the grounds that her opinions are inadmissible

[3] There is some confusion surrounding Plaintiffs' Designation of Rebuttal Expert Witnesses [71]. Plaintiffs' counsel asserts that he emailed the designation of Plaintiffs' rebuttal experts to Defendant's counsel on April 29, 2011, but that he "did not intend to file the Designation of Rebuttal Witnesses with the Court until he spoke with [her]" [70 at 4]. Plaintiffs' counsel asserts that Defendant's counsel did not return his telephone calls or email to discuss the designation. Plaintiffs' counsel contends that he drafted Plaintiffs' Designation of Rebuttal Expert Witnesses on April 29, 2011, after a telephone conversation with Defendant's counsel. On May 7, 2011, four days after Defendant filed its Motion to Strike and Exclude, Plaintiffs filed their Designation of Rebuttal Expert Witnesses, and also responded to Defendant's Motion to Strike and Exclude.

under the standards imposed by Federal Rules of Evidence 702 and 403, and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

On June 15, 2011, Defendant also moved for summary judgment on all of Plaintiffs' claims on the grounds that Plaintiffs cannot establish negligence without the testimony of Dr. Rosenthal and no act or omission concerning Plaintiffs' October 2007 Pap smear proximately caused Adams harm [75]. Defendant also argues that should the Court deny the motion to exclude Dr. Rosenthal, summary judgment should be granted in its favor on all claims related to the October 25, 2007, Pap smear.

On July 5, 2011, Plaintiffs filed a Re-Designation of Rebuttal Expert Witness Martha Bishop Pitman [85] seeking to offer Dr. Pitman's testimony to rebut the issues raised in Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [74].

On July 11, 2011, Plaintiffs moved to strike the declarations of Tiea L. Kesler ("Kesler") because she was not identified as a witness before the close of discovery and Defendant cannot show a substantial justification for its failure to timely identify her [90].

On July 19, 2011, the Court denied Plaintiffs' Motion for Leave to File Amended Complaint [41] and granted Defendant's Motion to Strike and Exclude

[68] any testimony by Drs. Pitman or Minkin as rebuttal expert witnesses. The Court did not address Plaintiffs' attempt to re-designate Dr. Pitman as a rebuttal expert to Defendant's challenge to Dr. Rosenthal, but did explicitly state: "Plaintiffs' proposed rebuttal witnesses also are not offered to rebut the testimony of Defendant's experts but to offer testimony to bolster the opinions of Plaintiffs' proposed experts in this case. That is, the testimony they offer is not rebuttal and is cumulative." (Order of July 19, 2011, [91] at 18-19).

On July 22, 2011, Defendant moved to strike the purported re-designation of Dr. Pitman as a rebuttal witness as untimely and on the ground that the delay in designating her as an expert witness, as the Court had already found in its Order, was unjustified [92].

On August 2, 2011, Plaintiffs sought leave to file a supplemental brief in opposition to Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [96]. On August 17, 2011, Defendant sought leave to file a surreply in further support of its Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [99].

On October 21, 2011, Defendant requested that the Court take judicial notice of actions involving Dr. Rosenthal in a separate case in state court [104].

II. DISCUSSION

The Court begins by addressing the numerous procedural motions filed by the parties to strike declarations and affidavits, and exclude from consideration the testimony of certain experts.

A. Plaintiffs' Motion to Strike Declarations of Tiea L. Kesler [90]

Rule 26(a)(1)(A)(i) of the Federal Rules of Civil Procedure governs the disclosure of witnesses that a party may use to support its claims or defenses and states that a party must provide to the other parties in its initial disclosures:

> the name and, if known, the address and telephone number of each individual likely to have discoverable information—along with the subjects of that information—that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment[.]

Rule 26(e)(1)(A) states that a party must supplement or correct its initial disclosures or responses:

> in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing[.]

Rule 37(c)(1) of the Federal Rules of Civil Procedure states that when a "party fails to provide information or identify a witness as required by Rule 26(a) or 26(e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified

or is harmless." "The burden of establishing that a failure to disclose was substantially justified or harmless rests on the nondisclosing party." Mitchell v. Ford Motor Co., 318 F. App'x. 821, 825 (11th Cir. 2009) (quoting Leathers v. Pfizer, Inc., 233 F.R.D. 687, 697 (N.D. Ga. 2006)).

Plaintiffs have moved to strike the declarations of Kesler on the grounds that she was not identified in Defendant's initial disclosures, Defendant has no substantial justification for the omission, and the use of her declarative testimony is not harmless "because of the close of discovery, the plaintiffs have not had the chance to inquire into or refute the alleged facts set forth in the declarations." (Pls.' Mot. to Strike Decls. of Tiea L. Kesler at 1-3).

Defendant argues that it was under no obligation to supplement its initial disclosures to specifically identify Kesler because she was named in lab operating procedures provided to Plaintiffs. (Def.'s Opp'n to Mot. to Strike Decls. of Tiea L. Kesler at 6). Defendant contends that the information contained in the declarations restates information that was already provided in the course of discovery and that any failure to identify Kesler in initial disclosures was harmless because many of the facts in her declarations are undisputed and have been admitted by Plaintiffs in connection with Defendant's Motion for Summary Judgment. (Id. at 6-9, 9 n.3). Defendant argues that any harm alleged by Plaintiffs in considering Kesler's

declarations in the absence of their ability to have questioned her findings is moot because another witness was questioned on similar matters by Plaintiffs and Plaintiffs could have noticed a deposition on the topics in Kesler's declarations. (Id. at 11).

Defendant also asserts that it was substantially justified in not naming Kesler in its initial disclosures because she did not have direct knowledge of the case and "what generalized knowledge she did have was duplicative of other disclosed witnesses." (Id. at 12). Defendant claims that it was substantially justified in not naming her because it was "merely a practical choice" to avoid "burdening the court with separate declarations from multiple witnesses with knowledge of various different aspects of the declaration's facts." (Id.).

The Court disagrees. As an initial matter, the Court rejects that because Kesler's name was mentioned in lab operating procedures disclosed to Plaintiffs during discovery, the requirement to supplement initial disclosures under Rule 26(e) was satisfied. Defendant failed to explicitly identify her as a fact witness and she was not identified as one based on the mere mention of her name in discovery documents. Defendant failed to comply with Rule 26.

The violation of Rule 26 was not harmless. Even though the information in her declarations may be cumulative of other information in the record, the fact is

that Plaintiffs were denied the opportunity during discovery to explore and seek additional information in depositions regarding Kesler's knowledge of the case. Plaintiffs did not have the opportunity to inquire into what Kesler knew and the failure to identify her as a fact witness is not harmless, especially considering that Defendant considers her declaration significant enough to rely on in support of its case.

Defendant also was not substantially justified in not naming her as a witness based on a practical choice to avoid redundant testimony from multiple witnesses. If Defendant made the practical choice not to name Kesler and not allow Plaintiffs the opportunity before the close of discovery to inquire and develop information regarding her knowledge of pertinent facts, Defendant must instead rely on the other sources of information that it did identify to Plaintiffs in the course of discovery. The Court finds that Rule 37(c)(1) requires that Kesler's declarations be stricken.

B. Defendant's Motion to Strike Plaintiffs' Re-Designation of Martha Bishop Pitman, M.D. and Pitman Affidavit [92]

On July 19, 2011, the Court struck and excluded any testimony from Dr. Pitman as an expert witness. By seeking to re-designate Dr. Pitman and submitting her affidavit, Plaintiffs simply are seeking to reoffer Dr. Pitman's expert opinion regarding acceptable methodology for reviewing Pap smear slides in the context of

litigation. (Pls.' Opp'n to Def.'s Mot. to Strike Pitman Aff. and Re-Designation at 2). Plaintiffs claim that Dr. Pitman's expert opinion is now relevant on a different issue—to rebut Defendant's argument that the only acceptable methodology of conducting a litigation review of Pap smear slides is through the blinded review[4] process recommended by the College of American Pathologists.

It is undisputed that Dr. Pitman was not timely disclosed as an expert witness, rebuttal or otherwise, pursuant to Rule 26 of the Federal Rules of Civil Procedure. As explained in the July 19, 2011, Order, discovery has closed and Plaintiffs did not comply with Rule 26 and the order of this Court regarding expert witness and fact witness disclosures. For the same reasons that were explained in the Court's July 19, 2011, Order and under Rule 37(c)(1), the Court finds again that Dr. Pitman is precluded from testifying as a witness in this case and her affidavit offering her expert opinion is stricken.

[4] Dr. Rosenthal defined a blinded review as "when you take the index case, the one that's under suspicion, mix that in with slides that are known to be negative, a number of those, and then you also put into the whole mix a few other abnormal slides so that you are checking out the accuracy of the cytotechs who are reviewing and looking for the missed case." (Dep. of Dr. Rosenthal at 113:21-114:7).

C. Plaintiffs' Request for Permission to File Supplemental Brief in Opposition to Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [96] and Defendant's Motion for Leave to File Surreply in Further Support of Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [99]

Both parties seek permission from the Court to file additional pleadings regarding Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D.

Neither the Federal Rules of Civil Procedure nor this Court's Local Rules authorize the filing of surreplies as a matter of right or in the ordinary course of litigation. See Byrom v. Delta Family Care--Disability and Survivorship Plan, 343 F. Supp. 2d 1163, 1188 (N.D. Ga. 2004); LR 7.1 C., 56.1 A., NDGa. Although the Court may permit the filing of a surreply, this discretion should be exercised in favor of allowing a surreply only where a valid reason for such additional briefing exists, such as where the movant raises new arguments in its reply brief or to allow a party to rebut new allegations made in an opposing party's surreply. See, e.g., Fedrick v. Mercedes-Benz USA, LLC , 366 F. Supp. 2d 1190, 1197 (N.D. Ga. 2005); Hammett v. Am. Bankers Ins. Co., 203 F.R.D. 690, 695 n.1 (S.D. Fla. 2001) ("Because Plaintiff presented new arguments and a new theory for certification in her Reply the Court will grant Defendants' Motion for Leave to File a Sur-Reply . . . ."); White v. Georgia, No. 1:07-cv-01739-WSD, 2007 WL 3170105, at *2-*3

(N.D. Ga. Oct. 25, 2007). This Court previously has warned that "[t]o allow such surreplies as a regular practice would put the court in the position of refereeing an endless volley of briefs." Garrison v. Northeast Georgia Med. Ctr., Inc., 66 F. Supp. 2d 1336, 1340 (N.D. Ga. 1999) (denying party's request for leave to file a surreply).

1. Plaintiffs' request to file a supplemental brief

Plaintiffs' basis for requesting permission to file a supplemental brief is that the original errata sheet from Dr. Rosenthal's deposition was not available prior to filing their response and the consideration of the errata sheet will clarify the portions of Dr. Rosenthal's deposition testimony that were relied upon by Defendant in its Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. (Pls.' Req. for Permission to File Supplemental Br. in Opp'n to Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D. at 1-3). In response, Defendant accuses Plaintiffs of delaying a decision on its Motion to Exclude by seeking to file a supplemental briefing that does not advance any new argument, alleges that the information in the errata sheet is not new and was known to Plaintiffs before filing its response, and claims that the errata sheet is immaterial to the arguments in its Motion to Exclude. (Def.'s Opp'n to Pls.' Req. for Permission to File Supplemental Br. in Opp'n to Def.'s Mot. to Exclude Pls.' Expert Dorothy

Rosenthal, M.D. at 1-9). In reply, Plaintiffs argue that the errata sheet did not become relevant until after Defendant's reply was filed and that the supplemental brief is necessary because Defendant, as the party taking the deposition, failed to file or advise the Court of the errata sheet. (Pls.' Reply in Supp. of their Req. to File Supplemental Br. in Opp'n to Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D at 2-3).

The Court is not persuaded by Plaintiffs' argument that the supplemental brief is necessary to present new information regarding the errata sheet. Plaintiffs were in possession of the errata sheet at the time they filed their response and the issues they now seek to raise through a supplemental brief could have been presented at an earlier time. Plaintiffs have not presented a valid reason for allowing additional briefing and have not demonstrated that a particular argument or representation made by Defendant in its reply brief warrants the filing of a supplemental brief. Accordingly, their request to file a supplemental brief is denied. To ensure the Court relies upon a complete and accurate record and with the aim of reaching a just result, the errata sheet will be considered in evaluating the deposition testimony of Dr. Rosenthal.

2. Defendant's request for leave to file a surreply

Defendant's basis for filing its surreply is: (1) that it "received new information about another case in which Dr. Rosenthal is testifying against LabCorp—information that shows a blinded review is feasible and confirms the utter unreliability of" her opinions; and, (2) that the late receipt of that information prevented Defendant from addressing it in earlier briefing. (Def.'s Mot. for Leave to File Surreply in Further Supp. of Mot. to Exclude Pls.' Expert Dorothy Rosenthal M.D. at 1-2). Plaintiffs oppose the filing of a surreply on the grounds that the information from an unrelated case adds nothing new to the matters before the Court and simply extends the arguments Defendant made previously. (Pls.' Resp. to Def.'s Mot. to File Surreply in Supp. of Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D. at 1-4).

The Court finds that Defendant has not presented a valid reason for allowing a surreply. The information from the unrelated case does not meaningfully add to the arguments of the parties. Whether some form of a blinded review of slides could be done, is feasible, or has been done in other cases—to include those involving Dr. Rosenthal—is undisputed. (Dep. of Dr. Rosenthal at 109:20-135:4). Furthermore, what a similarly-situated plaintiff does in an unrelated, state court case is irrelevant to the Court's evaluation of the facts at issue in this case and

whether Dr. Rosenthal's methodology in reviewing slides for the purposes of litigation is sufficiently reliable. Defendant's Motion for Leave to File Surreply in Further Support of Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. is denied.

D. Defendant's Request to Take Judicial Notice [104]

Federal Rule of Evidence 201 provides that a court may, in its discretion, take notice of certain facts without formal proof only where the fact in question is

> one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned.

Shahar v. Bowers, 120 F.3d 211, 214 (11th Cir. 1997) (quoting Fed. R. Evid. 201(b)). "[T]he kinds of things about which courts ordinarily take judicial notice are (1) scientific facts: for instance, when does the sun rise or set; (2) matters of geography: for instance, what are the boundaries of a state; or (3) matters of political history: for instance, who was president in 1958." Id.

"In order for a fact to be judicially noticed under Rule 201(b), indisputability is a prerequisite." United States v. Jones, 29 F.3d 1549, 1553 (11th Cir. 1994). "It is recognized that a court may take judicial notice of a document filed in another court not for the truth of the matters asserted in the other litigation, but rather to establish the fact of such litigation and related filings." Id. (internal citation

omitted); see also Stone v. Dewey, No. 1:10-cv-00159-MP-GRJ, 2011 WL 2784595, at *3 (N.D. Fla. July 14, 2011).

Defendant seeks judicial notice of a fact contained in a copy of supplemental objections and responses to a set of interrogatories filed by a plaintiff in a separate state court case where Dr. Rosenthal is acting as an expert. (Ex. A to Def.'s Req. to Take Judicial Notice). From this document, Defendant asks the Court to take judicial notice that blinded reviews of slides were conducted by Dr. Rosenthal in an entirely separate matter involving Defendant. (Id.). Plaintiffs argue the fact of which Defendant seeks the Court to take judicial notice is not indisputable because it is not clear what type of blinded reviews were conducted and whether they complied with the alleged mandatory standard for litigation review. (Pls.' Resp. and Objection to Def.'s Req. to Take Judicial Notice at 2).

The Court finds it cannot take judicial notice of the truth of matters asserted in a document filed in another ongoing case. See Jones, 29 F.3d at 1553; Stone, 2011 WL 2784595, at *3. The Court also finds that it is not undisputed that a blinded review occurred, based on the supplemental interrogatory responses and objections in the unrelated litigation. The fact a blinded review occurred is not "capable of accurate and ready determination by resort to sources whose accuracy

cannot reasonably be questioned." Fed. R. Evid. 201(b). Defendant's Request to Take Judicial Notice is denied.

E. Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [74]

1. Standard on expert testimony

In state medical malpractice actions brought in Georgia federal courts, "state law governs substantive issues and federal law governs procedural issues." McDowell v. Brown, 392 F.3d 1283, 1294 (11th Cir. 2004) (citing Erie R.R. Co. v. Tompkins, 304 U.S. 64 (1938)). Whether a medical expert is competent to testify is a substantive issue and governed by O.C.G.A. § 24-9-67.1 and federal court cases applying Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993); General Electric Co. v. Joiner, 522 U.S. 136 (1997); and Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137 (1999). See O.C.G.A. § 24-9-67.1; McDowell, 392 F.3d at 1294-95; Dukes v. Georgia, 428 F. Supp. 2d 1298, 1311 (N.D. Ga. 2006), aff'd, 212 F. App'x 916 (11th Cir. 2006); Mason v. Home Depot U.S.A., Inc., 658 S.E.2d 603, 608 (Ga. 2008). Once a district court determines that a medical expert is qualified to offer an opinion under O.C.G.A. § 24-9-67.1, the proposed expert testimony is then screened under Federal Rule of Evidence 702 and Daubert to determine if it is otherwise admissible. See McDowell, 392 F.3d at 1294-95.

Rule 702 of the Federal Rules of Evidence provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

To exercise properly its role under Daubert as a gatekeeper to the admission of scientific testimony, the Court must consider whether (i) the expert is qualified to testify regarding the matters he intends to address, (ii) the expert's methodology is sufficiently reliable, and (iii) the expert's testimony assists the trier of fact to understand the evidence or to determine a fact in issue. Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1340-41 (11th Cir. 2003).

Daubert sets forth a non-exclusive checklist for use in evaluating the reliability of scientific expert testimony. The factors include: (1) whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory

when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community. Daubert, 509 U.S. at 593-94. The Court is not required to consider each of these factors, "and a federal court should consider any additional factors that may advance its Rule 702 analysis." Quiet Tech. DC-8, Inc., 326 F.3d at 1341.

In applying the Daubert criteria and others that may be relevant, the Court must determine if the expert unjustifiably extrapolated from an accepted premise to an unfounded decision. See Gen. Electric Co., 522 U.S. at 146. That is, there must not be "too great an analytical gap between the data and the opinion proffered." Id. The Court must be assured the expert is using "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire, 526 U.S. at 152. "[N]ot only must each stage of the expert's testimony be reliable, but each stage must be evaluated practically and flexibly without bright-line exclusionary (or inclusionary) rules." Heller v. Shaw Indus., Inc., 167 F.3d 146, 155 (3d Cir. 1999). The focus must be on the principles and methodology and not the conclusions reached. Daubert, 509 U.S. at 595.[5]

[5] Neither Plaintiffs nor Defendant requested a hearing on Defendant's motion to exclude Dr. Rosenthal as an expert and having reviewed the record, the Court determines a hearing is not necessary to decide the motion.

2. Dr. Rosenthal's anticipated testimony and qualifications

Plaintiffs state that their expert, Dr. Rosenthal, "is one of the preeminent cytopathologists in the United States." (Pls.' Resp. to Def.'s Mot. to Exclude Dr. Rosenthal at 3). Dr. Rosenthal's anticipated testimony includes three expert opinions: (1) Defendant's cytotechnologists and pathologist violated the standard of care; (2) the violation of the standard of care caused a delay in the identification and treatment of Adams' cervical cancer and thus was a cause of her alleged injury; and, (3) Defendant's failure to have adequate continuous quality improvement ("CQI") efforts at its lab, at least partially, contributed to the failures of cytotechnologists to correctly diagnose Adams' Pap smear slides. (Report of Dorothy L. Rosenthal, M.D., FIAC, in the Case of Christina Adams ("Rosenthal Report") at 6-8).

Defendant does not dispute her qualifications under Georgia law or Daubert to offer an opinion on the standard of care. (Def.'s Reply in Further Supp. of Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D. at 2-6, 6 n.6). Defendant does contend that Dr. Rosenthal's opinions are inadmissible because the methodology used to develop her standard of care opinion is not sufficiently reliable under Daubert, she is not qualified to offer an opinion on causation and her opinion is cumulative and unreliable, and she is not qualified to offer an opinion on

the adequacy of quality control in Defendant's Pap smear screening process and her opinion is unreliable and does not relate to any material issue in dispute. (Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D. at 11-24).

The Court first considers whether Dr. Rosenthal's expert opinion regarding the standard of care for cytotechnologists is sufficiently reliable under Daubert. The Court begins its evaluation by reviewing cervical cancer and the manner in which cytotechnologists help detect and prevent cervical cancer through the examination of Pap smears.

3. Cervical cancer, Pap smears, and cytotechnologists

> Cervical cancer is a serious ailment worldwide and the second most common form of cancer afflicting women, with more than 15,000 new cases each year in the United States, and approximately 4,800 deaths annually. The disease is preceded by a precancerous, curable stage that progresses without symptoms over several years until it reaches an invasive stage that often leads to death. Thus, most deaths due to cervical cancer could be prevented with early detection and treatment.

Neuromedical Sys., Inc. v. Neopath, Inc., No. 96 Civ. 5245(JFK), 1998 WL 264845, at *2 (S.D.N.Y. May 26, 1998).

"Cervical cancer is screened by examining cervical tissue most often taken in the form of a Papancolaou ('Pap') smear." Cytyc Corp. v. TriPath Imaging, Inc., 505 F. Supp. 2d 199, 207 (D. Mass. 2007).

> A Pap smear is obtained by scraping the surface of a woman's cervix to collect a sample of cells that are then smeared onto a microscope

> slide and fixed with a preservative. The slide is then sent to a laboratory and viewed manually through a laboratory microscope by a cytotechnologist to determine if the sample includes cells, such as premalignant or malignant cells, bearing evidence of abnormality.

Neuromedical Sys., Inc., 1998 WL 264845, at *2. Pap smear abnormalities are characterized as atypical glandular cells ("AGC"), low-grade squamous intraepithelial lesions ("LSIL"), high-grade squamous intraepithelial lesions ("HSIL"), and atypical squamous cells ("ASC"). (Ex. A to Def.'s Opp'n to Pls.' Mot. to Exclude Test. of Def.'s Pathologist Regarding Standard of Care). ASC can be subcategorized as ASC of undetermined significance ("ASC-US"), or as cannot exclude HSIL ("ASC-H"). (Id.).

"A cytotechnologist is responsible for screening and preliminarily diagnosing gynecologic and non-gynecologic specimens for evidence of disease and malignancy." Adams v. Upper Chesapeake Medical Center, Inc., Civil Action No. AMD 08-346, 2009 WL 997103, at *1 n.1 (D. Md. Apr. 14, 2009).

> The work of cytotechnologists can be tedious, tiring and difficult. A single Pap smear slide may contain a few hundred thousand cells that may be arranged in an overlapping manner, and only a dozen of those cells may have indications of cancerous or precancerous conditions. Indeed, a sizable percentage of slides that are initially classified by cytotechnologists as normal actually contain cells with indications of cancerous or precancerous conditions. Such slides, mistakenly diagnosed as normal, are known as "false negatives." The 1996 Cervical Cancer Consensus Conference reported that as many as 20% of all Pap smear reports are false negatives, and some laboratories have had false negative rates as high as 50%. Thus, while the manual

> Pap smear test has increased the detection of cervical cancer, this test has also been plagued by a high false negative rate in the manual screening process.

Neuromedical Sys., Inc., 1998 WL 264845, at *3 (internal citation omitted). False negatives can occur for a number of reasons, to include sampling, locator, and interpretive errors. (Pls.' Resp. to Def.'s Mot. to Exclude Dr. Rosenthal at 2-3).

"All positive findings are referred to pathologists for further evaluation and action." Moultrie v. Laboratory Corp. of Am., No. Civ.A.SA03-CA-383-XR, 2004 WL 957941, at *1 n.1 (W.D. Tex. May 5, 2004). "Various types of cell abnormalities exist, ranging from mild to full-blown cancers. A mild abnormality is referred to as 'low grade' and a serious abnormality as 'high grade.' Failure to note properly a high grade abnormality may have significant consequences, including the possibility of a missed cancer diagnosis." Young v. Shore Health System, Inc., 305 F. Supp. 2d 551, 555 (D. Md. 2003).

Quality control of laboratories and cytotechnologists is provided for by the labs themselves, the cytology profession, and federal regulatory agencies. (Dep. of Dr. Rosenthal at 293:2-6). Cytotechnologists are board certified through training programs and must pass a proficiency exam. (Id. at 195:6-12). Additionally, "[p]ursuant to the 1988 amendments to the Clinical Laboratory Improvement Act, 42 U.S.C. § 263a, at least ten percent of the slides that a cytotechnologist screens

as negative or normal must be rescreened. Rescreening is generally performed by the cytotechnologist supervisor or pathologist." Young, 305 F. Supp. 2d at 556.

4. Dr. Rosenthal's preparation of her expert report

On April 4, 2011, Dr. Rosenthal completed her expert report. (Rosenthal Report at 1). In it, she states her first expert opinion that errors in interpreting Adams' Pap smear slides were committed by cytotechnologists that "fell below the standard of care for a cytotechnologist." (Id. at 6-7). Dr. Rosenthal defines the standard of care for a cytotechnologist 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 that needs to be referred to the—either supervisory of cytotech [sic], whatever is in process in the lab, or to the pathologist." (Dep. of Dr. Rosenthal at 194:12-18). She also states that her further expert opinion is that Adams' October 25, 2007, Pap smear was misinterpreted by a pathologist, Dr. Arthur R. Summerlin, M.D., who is employed by Defendant and that Dr. Summerlin's failure to correctly read the Pap smear submitted for his review "fell below the standard of care for a pathologist." (Rosenthal Report at 7).

Finally, Dr. Rosenthal expresses the opinion that Defendant had "inadequate continuous quality improvement (CQI) efforts" and that misinterpretation of the

slides by cytotechnologists was, "at least partially," the result of Defendant's inadequate CQI program. (Id.).

Dr. Rosenthal testified at her deposition how she formed her standard of care opinion regarding Defendant's cytotechnologists. She explained how she came to Atlanta and reviewed at Defendant's lab the specific Pap smear slides that Plaintiffs submit should have been identified by Defendant's cytotechnologists as containing cells that warranted further review by a pathologist. (Dep. of Dr. Rosenthal at 139:5-140:12). Dr. Rosenthal's review of these slides lasted about ninety minutes. (Id. at 140:10-12). Dr. Rosenthal did not review any slides other than those resulting from Pap smears taken from Ms. Adams. (Id. at 200:13-15). Dr. Rosenthal conducted her review by "plac[ing] the slides under a microscope, [where she then] assessed the number and appearance of abnormal cells, and, based upon her education, training and experience as a physician,[6] reached a diagnosis." (Pls.' Resp. to Def.'s Mot. to Exclude Dr. Rosenthal at 14).

Dr. Rosenthal reviewed the slides knowing they were of Adams' prior Pap smear tests, that Adams had been diagnosed with cervical cancer, that her examination was in connection with potential litigation, and that Defendant's reviewing cytotechnologists had previously screened the Pap smear slides and had

[6] She did not review them based upon her training or experience as a cytotechnologist screener.

not identified any abnormal cells. (Dep. of Dr. Rosenthal at 139:5-140:12, 144:10-13; Rosenthal Report at 1-2; Aff. of Dr. Dorothy L. Rosenthal, M.D., FIAC ¶¶ 3, 8). Dr. Rosenthal's analysis led her to conclude that the Pap smears she reviewed had abnormal cells and that the cytotechnologists who first reviewed them should have come to the same conclusion she had and thus should have referred the Pap smears to a pathologist for further evaluation. (Rosenthal Report at 6-7). This examination is the basis for Dr. Rosenthal's opinion that Defendant's cytotechnologists interpretation of Adams' Pap smear slides fell below the standard of care. (Id. at 6-8).

5. Review bias and the College of American Pathologists and the American Society of Cytopathology litigation review criteria

Dr. Rosenthal is a member of the preeminent peer-professional organizations in the area of pathology and cytopathology, to include the American Society of Clinical Pathology, International Academy of Cytology, College of American Pathologists, and American Society of Cytopathology. (Dep. of Dr. Rosenthal at 86:6-94:7). These organizations establish professional standards for pathologists and cytopathologists. (Id. at 94:8-11). The College of American Pathologists establishes standards for pathologists, and the American Society of Clinical Pathology and American Society of Cytopathology establish standards for cytotechnologists. (Id. at 87:21-88:14).

Because the Pap smear "is a screening test that involves subjective interpretation by a cytotechnologist or pathologist of the thousands of cells that are present on a typical gynecologic cytology" specimen, the College of American Pathologists and American Society of Cytopathology have both noted there is an irreducible false-negative error rate of around 5% in reading Pap smear slides caused by "[m]any factors, including the subjectivity involved in interpreting difficult cases and sampling problems with specimen collection." (Exs. A-3 and A-4 to Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D.).[7]

This irreducible error rate, caused by many factors, presents problems in determining when a cytotechnologist or pathologist violates the standard of care in reviewing Pap smear slides. (Id.). Because of the uniqueness of Pap smears and their role as a screening device for cervical cancer, the College of American Pathologists and American Society of Cytopathology recommend pathologists or cytotechnologists who review Pap smear slides in the context of litigation and potential litigation follow specific guidelines. (Id.). These governing organizations believe adhering to their guidelines is necessary to ensure there is an unbiased, objective, and scientific method for reviewing questioned cases in the

[7] This error rate is considered acceptable in the pathology and cytotechnology communities because of the benefit provided by the cost and time-efficient screening of volumes of Pap smears in an effort to detect as many abnormal Pap smears as possible.

context of litigation that is fair to both the patient and the reviewing laboratory. (Id.).

The guidelines issued by the College of American Pathologists, an organization of which Dr. Rosenthal is a member, are most relevant to the manner in which she conducted a litigation review of Adams' Pap smear slides.[8] The

[8] The Court notes that the guidelines issued by the American Society of Cytopathology governing cytotechnologists are substantially similar to those issued by the College of American Pathologists. Like the College of American Pathologists, the American Society of Cytopathology guidelines address "the inherent limitations of [the Pap smear] screening test and [need for] an objective and scientific method for review of questioned cases that is fair to both the patient and the laboratory." (Ex. A-4 to Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D.). The American Society of Cytopathology Guidelines for Review of [Gynecological] Cytology Samples in the Context of Litigation or Potential Litigation state that:

> Pap test slides being assessed for an objective unbiased basis on which to assert a violation of a reasonable prudent practitioner standard of practice should first be reviewed without knowledge of clinical outcome and in an environment that simulates the normal screening practice. A violation of a reasonable prudent practitioner standard of practice based on how specific Pap tests were screened and interpreted can only be established through an unbiased blinded rescreening review process that includes the contested case as one of a number of normal and abnormal [gynecological] cytology samples representing a variety of disease states. 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.

(Id.).

College of American Pathologists Guidelines for the Review of Pap Tests in the Context of Litigation or Potential Litigation state that:

> 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 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.
>
> . . .
>
> One 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. 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 review process conducted by several qualified reviewers. Negligence should not be inferred unless there is a consistent finding by the reviewers that the laboratory failed to identify clinically significant abnormalities.
>
> . . .
>
> The standard of care should be that of the reasonable and prudent practitioner. Focussed [sic] 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.

(Ex. A-3 to Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D.).

Within the practice of pathology, even Dr. Rosenthal acknowledges that the criteria for conducting research and analysis that satisfies the standards of peer-

review includes the use of controls; an ability to analytically validate findings, to include quantifiable reproducibility; and the use of blinded reviews. (Dep. of Dr. Rosenthal at 104:20-105:11). Dr. Rosenthal admits that these characteristics in conducting research and analysis in the area of pathology are important to ensure that there is integrity in the process and the results are reliable. (Id. at 105:9-106:22). She notes further that conducting research and analysis in this reliable manner should ideally allow for another pathologist to objectively test the technique or theories applied and reach the same conclusions. (Id. at 107:1-9).

Dr. Rosenthal agrees that in the context of litigation "all cases of alleged malpractice against a cytotechnologist or a pathologist should be reviewed by a panel" comprised "of individuals trained and experienced in cytopathology before proceeding with civil litigation relating to gynecologic cytology specimen." (Id. at 108:22-109:15). She testified further that "[t]he best way to review a Pap smear in the context of litigation is to do a blinded review." (Id. at 114:8-12). Dr. Rosenthal generally agrees with the guidelines established by the College of American Pathologists and American Society of Cytopathology, but claims in this case that a blinded review is not the only approach that may be used in the context of litigation to establish a violation of the standard of care because of the practical difficulties involved in setting up a blinded review and that it would cost around

$9,000. (Id. at 110:1-111:11, 117:1-125:21). Her testimony seems to be that the litigation standard within the practice of pathology is a blinded review for the integrity and fairness reasons she noted, but that those standards can be displaced with a review-biased,[9] non-blinded review of Pap smears of a known cervical cancer patient because it is more practical and less expensive to do so.

The record also is clear that Defendant did not prevent Dr. Rosenthal from conducting a blinded review of Adams' slides. (Id. at 125:1-3, 330:9-13). Dr. Rosenthal acknowledges that she did consider conducting and did not attempt to conduct a blinded review. (Id. at 130:4-131:10). She also did not reach out to anyone in the area of pathology or cytotechnology for assistance in setting up a blinded review. (Id.). Dr. Rosenthal admitted that if she had the capabilities and resources to conduct a blinded review in this case, she would have conducted one. (Id. at 129:21-130:3, 131:11-14).

Dr. Rosenthal has conducted modified blinded reviews in the past and acknowledges that some form of blinded review is preferable to having a single pathologist conduct a retrospective review with knowledge that the slides in question are from a patient who developed cancer. (Id. at 112:3-18). In this case,

[9] Dr. Rosenthal defines review bias or hindsight bias as "[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." (Dep. of Dr. Rosenthal at 79:9-22).

Dr. Rosenthal contends that it was a lack of resources that persuaded her not to conduct a blinded review and not because her "interpretation of the slides [was] so right that it [didn't] need a blinded review. (Id. at 129:21-130:3).

6. Reliability of Dr. Rosenthal's slide review methodology

Dr. Rosenthal's methodology is not sufficiently reliable and falls short of what is required to offer an expert opinion on the standard of care for a cytotechnologist.

The deficiency with Dr. Rosenthal's methodology is that it is an *ipse dixit* assessment that is devoid of any methodology that would allow another expert to challenge it in any objective sense, precisely what a blinded review allows and which is the standard set by the profession in which Dr. Rosenthal practices. Dr. Rosenthal simply did not conduct her research and analysis of Adams' slides in the manner that would satisfy the generally accepted standards in the area of pathology or cytotechnology and did not engage in a peer-reviewable evaluation because her opinion was reached without the implementation of any objective standards or controls. Daubert, 509 U.S. at 593-94; Kumho, 526 U.S. at 152.[10]

[10] The Court rejects Plaintiffs' argument that "a qualified professional's opinion testimony about the standard of care is one of the 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." (Pls.' Resp. to Def.'s Mot. to Exclude Dr. Rosenthal at 13 (quoting Kilpatrick v. Breg, Inc., 613 F.3d

Within the areas of pathology and cytotechnology, it is accepted that when an unblinded review of Pap smear slides is conducted there is a known potential error and unreliability in the technique because review bias in inherent. (Exs. A-3 and A-4 to Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D.; Dep. of Dr. Rosenthal at 79:9-80:11). The need for a blinded review was particularly acute here where Dr. Rosenthal acknowledged her philosophical "bent toward a plaintiff who has developed cervical cancer." (Dep. of Dr. Rosenthal at 159:13-22). She testified further about her bent saying: "when a woman is diagnosed with cervical cancer, the system has failed her." (Id.). Dr. Rosenthal defines herself as a "patient's advocate" who is obligated to "stand up" for women with cervical cancer. (Id.). She explained what she means by standing up for women with cancer: "I don't think it is up to me alone, but as I said I use these slides for teaching. I went into medicine to help patients, not to help my defendant colleagues. Not that I won't help them, but if I am asked by a plaintiff's attorney to help a patient, I will." (Id. at 160:22-161:5).

1329, 1336 (11th Cir. 2010) (internal quotation omitted)). Plaintiffs selectively quoted Kilpatrick and omitted the remainder of the sentence that states: "but at all times the district court must still determine the reliability of the opinion, not merely the qualifications of the expert who offers it." 613 F.3d at 1336. The Court has conducted that inquiry and found that Dr. Rosenthal's methodology is not sufficiently reliable.

For these and other reasons of scientific integrity, the technique of using a retrospective review by a single pathologist for the purposes of litigation has been explicitly rejected as unreliable by the governing professional bodies because it simply does not account for the same conditions and circumstances under which a cytotechnologist originally evaluated the slides. (Exs. A-3 and A-4 to Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D.; Dep. of Dr. Rosenthal at 79:9-80:11).

It 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." See, e.g., Critser v. McFadden, 593 S.E.2d 330, 332 (Ga. 2004). Unlike the litigation slide review guidelines promulgated by the College of American Pathologists, Dr. Rosenthal's methodology and opinion was based on a focused, retrospective slide review with knowledge of Adams' cancer diagnosis. Dr. Rosenthal's approach did not account for the similar conditions and surrounding circumstances under which a cytotechnologist works and originally viewed the slides.

The standard of care about which Dr. Rosenthal seeks to offer her opinion is the standard of care for cytotechnologists who screen slides in a laboratory for the purpose of seeking to identify slides to be referred to a pathologist for a

pathological review to determine if the slide contains cancer cells. These cytotechnologists perform an important role in the Pap smear slide review process, but the role is very different from that of the pathologist. Cytotechnologists review a large number of Pap smear slides, only a small subset of which contain cells that might require further review by a pathologist. Thus, their professional competence is the ability to identify the few slides out of many that warrant review by a doctor. The pathologist reviewer has an entirely different function: to review slides that have been identified as abnormal or at least which suggest the possibility that cancer is present. The pathologist's function is materially different in function and scope than that of the cytotechnologist. And whether the standard of care is breached is an entirely different evaluation.

Plaintiffs argue that Dr. Rosenthal may opine on any part of this Pap smear slide review process because it is encompassed within the area of pathology. Plaintiffs broadly state that "[a] qualified doctor's opinion about the standard of care within his or her specialized knowledge is routinely admitted because the training and experience which generates the qualifications also generates reliable knowledge about the standards of the profession." (Pls.' Resp. to Def.'s Mot. to Exclude Dr. Rosenthal at 8-9). This conclusory statement would apply if Dr. Rosenthal was limiting her opinion to the standard of care of pathologists

performing the post-screening review function. The argument advanced by Plaintiffs ignores that the screening of slides is a wholly different process requiring a different standard of care because the role of cytotechnologists is wholly different. The cytotechnologists function is to find the few among the many and not to determine if the few do indeed present cancer cells. It is because these functions are so different that the national professional organizations—of which Dr. Rosenthal is a member and actively participates—have specifically established guidelines for professionals in the areas of pathology and cytotechnology to utilize when evaluating Pap smear slides for the purposes of litigation and whether the standard of care has been violated in the Pap smear screening process. That process requires the use of a blinded review screening and it was that process that Dr. Rosenthal chose, for cost-efficiency and other reasons, not to follow.

Had she conducted a blinded review and reached an opinion based on it, her testimony regarding whether the standard of care was breached in the screening process by cytotechnologists would likely be reliable because it would have taken into account the same conditions and circumstances under which the slides at issue here were reviewed by Defendant's cytotechnologists. Of course, if no slides were identified as abnormal in a blinded review screening process, this would be a very different case. We will never know what a blinded review—or even a modified

blinded review—would have shown because of Dr. Rosenthal's choice not to follow the evaluation process established by her profession and the experts in it. Dr. Rosenthal's election is regrettable.

Dr. Rosenthal's methodology for reaching her opinion in this case falls outside the standards of her profession, does not represent the "same level of intellectual rigor that characterizes the practice of an expert" in the areas of pathology and cytotechnology, is subject to review bias, and thus is not sufficiently reliable to allow a jury to consider her expert opinion on the matter. Daubert, 509 U.S. at 593-94; Kumho, 526 U.S. at 152. On the record here, the Court concludes Dr. Rosenthal may not offer a cytotechnologist standard of care opinion regarding the interpretation of Adams' Pap smear slides based on the methodology she elected to apply.[11]

7. Dr. Rosenthal's qualifications to offer an opinion on causation

Plaintiffs also seek to offer Dr. Rosenthal's opinion regarding what a competent, treating gynecologist or oncologist would have done upon receipt of abnormal Pap smear results. (Rosenthal Report at 8). Defendant's challenge her

[11] The Court does not hold 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.

competency to testify regarding causation and this is a threshold question that must be answered by the Court. See McDowell, 392 F.3d at 1294-95; (Def.'s Mot. to Exclude Pls.' Expert Dorothy Rosenthal, M.D. at 19). Whether Dr. Rosenthal is competent to testify regarding what Adams' treating gynecologist or oncologist would have done upon receipt of abnormal Pap smear results is governed initially by Georgia law:

> Notwithstanding . . . in professional malpractice actions, the opinions of an expert, who is otherwise qualified as to the acceptable standard of conduct of the professional whose conduct is at issue, shall be admissible only if, at the time the act or omission is alleged to have occurred, such expert:
>
> > (1) Was licensed by an appropriate regulatory agency to practice his or her profession in the state in which such expert was practicing or teaching in the profession at such time; and
> >
> > (2) In the case of a medical malpractice action, had actual professional knowledge and experience in the area of practice or specialty in which the opinion is to be given as the result of having been regularly engaged in:
> >
> > > (A) The active practice of such area of specialty of his or her profession for at least three of the last five years, with sufficient frequency to establish an appropriate level of knowledge, as determined by the judge, in performing the procedure, diagnosing the condition, or rendering the treatment which is alleged to have been performed or rendered negligently by the defendant whose conduct is at issue; or
> > >
> > > (B) The teaching of his or her profession for at least three of the last five years as an employed member of the

> faculty of an educational institution accredited in the teaching of such profession, with sufficient frequency to establish an appropriate level of knowledge, as determined by the judge, in teaching others how to perform the procedure, diagnose the condition, or render the treatment which is alleged to have been performed or rendered negligently by the defendant whose conduct is at issue.

O.C.G.A. § 24-9-67.1(c); McDowell, 392 F.3d at 1295. "[T]he area or specialty at issue and the treatment allegedly performed negligently can be gleaned from the complaint, the attached affidavits, and the pretrial order." Anderson v. Mountain Management Servs., Inc., 702 S.E.2d 462, 465 (Ga. Ct. App. 2010); see also Spacht v. Troyer, 655 S.E.2d 656, 659 (Ga. Ct. App. 2007).

Under O.C.G.A. § 24-9-67.1, "it is the expert's qualifications, rather than the doctor's specialty or area of practice, that controls whether the trial court should allow the expert's testimony." Mays v. Ellis, 641 S.E.2d 201, 203 (Ga. Ct. App. 2007) (quoting Cotten v. Phillips, 633 S.E.2d 655, 659 (Ga. Ct. App. 2006)). A testifying medical expert may offer an opinion outside of his own practice or specialty, but must be found qualified by the court in the area of practice or specialty in which the opinion is to be given. Cotten, 633 S.E.2d at 658. To qualify to offer an expert opinion outside of a physician's practice or specialty, "even if the expert is generally qualified as to the acceptable standard of conduct of the medical profession in question," the requirements of O.C.G.A. § 24-9-

67.1(c)(2) must be satisfied. Nathans v. Diamond, 654 S.E.2d 121, 123 (Ga. 2007).

In setting statutory requirements for expert medical testimony, the Georgia "General Assembly intended to require a [party] to obtain an expert who has significant familiarity with the area of practice in which the expert opinion is to be given." Id. "Only a doctor who has an appropriate level of knowledge, as determined by the judge, and who has significant familiarity with the area of practice in which the expert opinion is to be given is authorized to judge another doctor's performance in that area of practice." Hope v. Kranc, 696 S.E.2d 128, 131 (Ga. Ct. App. 2010) (internal quotation and citations omitted).

Plaintiffs' Complaint here asserts that the negligence of Defendant's cytotechnologists and pathologist caused or contributed to the delay in diagnosing and treating Adams' cancer. (Compl. ¶ 6). Dr. Rosenthal's proffered causation opinion pertains to the acts or omissions of gynecologists and oncologists relating to the treatment of Adams. Thus, the areas of gynecology and oncology are at issue in evaluating whether Dr. Rosenthal is qualified to offer her causation opinion. See Anderson, 702 S.E.2d at 465.

Dr. Rosenthal is a pathologist and has not rendered treatment to gynecology or oncology patients. O.C.G.A. § 24-9-67.1(c)(2)(A). She does not have

experience teaching others how to render treatment to gynecological or oncology patients, and she has not and does not treat patients with cervical lesions or cancer. O.C.G.A. § 24-9-67.1(c)(2)(B); (Dep. of Dr. Rosenthal at 21:2-23:7). Dr. Rosenthal does not consider herself qualified to give any opinions outside the area of pathology or cytopathology. (Id. at 58:5-7, 227:21-228:21, 230:8-17, 235:7-16, 314:7-8). Plaintiffs appear to want Dr. Rosenthal to offer an opinion on what treatment Ms. Adams would have been given by a gynecologist or oncologist had Defendant's cytotechnologists and pathologist identified alleged abnormal cells on her Pap smears and reported that information to Ms. Adams' treating physician. (Id. at 24:1-25:7; Rosenthal Report at 8).

Dr. Rosenthal's background and experience does not qualify her under either Georgia law or Daubert to offer an opinion on causation based on what a gynecologist or oncologist should have done upon being presented with abnormal Pap smear results and what medical consequences and processes would have occurred upon that Pap smear information being communicated to him, her, or them. See O.C.G.A. § 24-9-67.1(c)(2); Daubert, 509 U.S. at 593-94; Dukes, 428 F. Supp. 2d at 1311; Mason, 658 S.E.2d at 608; Nathans, 654 S.E.2d at 123; Hope, 696 S.E.2d at 131. The Court thus finds that Dr. Rosenthal is unqualified to offer an opinion regarding causation and what Adams' treating gynecologist or

oncologist should have done after an abnormal Pap smear because her experience as a pathologist is not sufficient to qualify her to offer an opinion regarding the course of treatment a gynecologist or oncologist should have followed after an abnormal Pap smear result. That conclusion is supported here where Adams' pregnancy and its resulting physiological effects made it necessary to take into account the full scope of gynecological considerations that would impact how to treat a pregnant or post-partum woman who received an abnormal diagnosis on her Pap smear test. (Report of George M. Kemp, M.D., Concerning Christina Adams ("Kemp Report") at 2). These unique considerations are clearly beyond the scope of Dr. Rosenthal's knowledge regarding what a pathologist would generally recommend to a gynecologist when reporting an abnormal Pap smear diagnosis.

8. Dr. Rosenthal's qualifications to offer an opinion on quality control

Finally, Plaintiffs seek to have Dr. Rosenthal offer her opinion on the adequacy of quality control processes at Defendant's laboratory. Admitting that Defendant's laboratory complies with all applicable regulations and certifications, Dr. Rosenthal nonetheless opines that Defendant had inadequate quality control because it failed "to encourage their professional staff to self-educate" or "provide adequate substantive feed back [sic] to their staff as to errors they may have made." (Rosenthal Report at 8; Dep. of Dr. Rosenthal at 295:15-18).

Dr. Rosenthal has not supervised a lab since 2003 and offers her subjective, conclusory opinion based generally upon her "[f]orty plus years of experience." (Dep. of Dr. Rosenthal at 298:18-22, 301:19). Her opinion is not based on a sufficient statistical or other credible analysis and was determined after a review of the cytotechnologists personnel files and performance history. (Id. at 291:13-292:16). Running a laboratory in the past and generally being responsible for quality assurance and control during a career does not qualify her to offer a continuous quality improvement expert opinion regarding a laboratory that reviews Pap smears. Similarly, conducting a review of personnel files and performance history without any detailed statistical analysis is not a sufficient methodology to develop a reliable CQI opinion.

Additionally, Plaintiffs have not claimed that Defendant's inadequate quality control constitutes an act of negligence that caused Adams' cervical cancer. (Compl. at 1-4). Dr. Rosenthal's opinion on quality control is not relevant or helpful because Plaintiffs' litigation theory is that Defendant's cytotechnologists and pathologist breached their duty of care and that this breach caused Adams' cervical cancer. (Id.). Plaintiffs' claims against Defendant are based on its vicarious liability for the acts of its cytotechnologists and pathologist. (Id. ¶ 9). Dr. Rosenthal is unable to connect any alleged shortcoming in CQI at Defendant's

laboratory to the alleged negligence of the cytotechnologists and pathologist at issue in this case. (Dep. of Dr. Rosenthal at 303:20-304:1).

The Court thus finds that Dr. Rosenthal does not have sufficient experience in the area of quality control to qualify as an expert; that her methodology is unreliable because it is not based on a sufficient statistical or other credible analysis; and, that her CQI opinion will not assist the trier of fact in understanding the evidence or determining a fact in issue. Fed. R. Evid. 401, 403, 702; Daubert, 509 U.S. at 593-94; Quiet Tech. DC-8, Inc., 326 F.3d at 1340-41.

F. Defendant's Motion for Summary Judgment [75]

1. Summary judgment standard

Upon motion by a party, a court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Parties "asserting that a fact cannot be or is genuinely disputed must support that assertion by . . . citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1).

The party seeking summary judgment bears the burden of demonstrating the absence of a genuine dispute as to any material fact. Herzog v. Castle Rock Entm't, 193 F.3d 1241, 1246 (11th Cir. 1999). Once the moving party has met this burden, the non-movant must demonstrate that summary judgment is inappropriate by designating specific facts showing a genuine issue for trial. Graham v. State Farm Mut. Ins. Co., 193 F.3d 1274, 1282 (11th Cir. 1999). Non-moving parties "need not present evidence in a form necessary for admission at trial; however, [they] may not merely rest on [their] pleadings." Id. "A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence." Fed. R. Civ. P. 56(c)(2).

The Court must view all evidence in the light most favorable to the party opposing the motion and must draw all inferences in favor of the non-movant, but only "'*to the extent supportable by the record*.'" Garczynski v. Bradshaw, 573 F.3d 1158, 1165 (11th Cir. 2009) (quoting Scott v. Harris, 550 U.S. 372, 381 n.8 (2007) (emphasis in original)). "[C]redibility determinations, the weighing of evidence, and the drawing of inferences from the facts are the function of the jury . . . ." Graham, 193 F.3d at 1282. "If the record presents factual issues, the court must not decide them; it must deny the motion and proceed to trial." Herzog, 193 F.3d at 1246. But, this requirement "extends only to 'genuine' disputes over

material facts," meaning "more than 'some metaphysical doubt as to the material facts.'" Garczynski, 573 F.3d at 1165 (quoting Scott, 550 U.S. at 380). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

2. Plaintiffs' claims based on violations of the standard of care by Defendant's cytotechnologists

"In a medical malpractice case, the plaintiff must present expert medical testimony establishing that the defendant's negligence either proximately caused or contributed to his injuries." Beasley v. Northside Hosp., 658 S.E.2d 233, 236 (Ga. Ct. App. 2008). Having found Dr. Pitman may not testify as an expert witness and that Dr. Rosenthal may not offer an expert opinion regarding any violation of the standard of care for a cytotechnologist in the reading Adams' Pap smear slides, Plaintiffs are unable to present any evidence on that essential element of their claims involving negligence by Defendant's cytotechnologists. Summary judgment is granted to Defendant on all claims involving a violation of the standard of care by its cytotechnologists.

3. Plaintiffs' claims based on violations of the standard of care by Defendant's pathologist

"To recover damages in a tort action, a plaintiff must prove the defendant's negligence was both the 'cause in fact' and the 'proximate cause' of the injury." Atlanta Obstetrics & Gynecology Gr., P.A. v. Coleman, 398 S.E.2d 16, 17 (Ga. 1990); see also Johns v. Jarrard, 927 F.2d 551, 558 (11th Cir. 1991) ("[A] plaintiff in a medical malpractice suit must not only demonstrate that [a defendant] breached the applicable standard of care, but must also prove that that breach proximately caused the alleged injury."). "Proximate cause 'is that which in the natural and continuous sequence, unbroken by other causes, produces an event, and without which the event would not have occurred.'" Zwiren v. Thompson, 578 S.E.2d 862, 865 (Ga. 2003) (quoting T.J. Morris Co. v. Dykes, 398 S.E.2d 403, 406 (Ga. 1990)).

"[W]hether proximate cause exists in a given case is a mixed question of law and fact. It requires both fact-finding in the 'what happened' sense, and an evaluation of whether the facts measure up to the legal standard set by precedent." Atlanta Obstetrics, 398 S.E.2d at 17. Plaintiffs bear the burden of proving causation and "must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a cause in fact of the result. A mere possibility of such causation is not enough; and

when the matter remains one of pure speculation . . . it [is] the duty of the court to grant summary judgment for the defendant." Shadburn v. Whitlow, 533 S.E.2d 765, 767 (Ga. Ct. App. 2000) (quoting Head v. Sears Roebuck & Co., 503 S.E.2d 354, 355 (Ga. Ct. App. 1998)).

Plaintiffs assert that Defendant's pathologist, Dr. Summerlin, violated the standard of care for a pathologist by misinterpreting Adams' October 25, 2007, Pap test as atypical squamous cells of undetermined significance ("ASC-US"). According to Dr. Rosenthal, "the test actually contained thick fragments of epithelium, most probably representing HSIL," and thus Plaintiffs argue Defendant's pathologist should have identified the cells as high-grade squamous intraepithelial lesion ("HSIL") and the failure to do so constituted negligence. (Rosenthal Report at 4, 7). Plaintiffs' experts both offer the opinion that if Dr. Summerlin had interpreted the Pap smear as HSIL, Adams' treating physician "would have performed a colposcopy and/or a biopsy." (Def.'s Statement of Undisputed Material Facts ¶¶ 14-15). It is, however, undisputed that Adams did have a colposcopy and biopsy performed after Dr. Summerlin allegedly misinterpreted her Pap smear as ASC-US. (Id. ¶¶ 6, 16). Furthermore, Plaintiffs' causation expert, Dr. George M. Kemp, M.D., does not claim that Dr. Summerlin's diagnosis resulted in any delay, but rather that it was Defendant's

cytotechnologists interpretations of normal on all the other Pap smear slides in January 2006, January 2007, March 2008, and September 2008 that caused a delay in diagnosis of Adams' cervical cancer. (Kemp Report at 2-3).[12] Thus, Plaintiffs do not offer any evidence that Dr. Summerlin's ASC-US diagnosis caused a delay in these procedures.[13]

Assuming all facts in the non-movant's favor and that Dr. Summerlin violated the standard of care by classifying the slide as ASC-US instead of HSIL, there is no evidence that Dr. Summerlin's ASC-US diagnosis caused any harm because it is undisputed that the ASC-US classification did not result in Adams receiving any different treatment than she would have received if her Pap smear had been classified as HSIL as Plaintiffs contend.[14] Because Ms. Adams'

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[12] The Court has also reviewed Dr. Kemp's deposition and finds that his deposition testimony is consistent with the opinion in his written report that the cause of the delay in diagnosing Adams' cancer did not involve Dr. Summerlin's diagnosis in October 2007, but was caused by the misinterpretation of Adams' Pap smear slides by Defendant's cytotechnologists. (Dep. of Dr. Kemp at 85:1-10, 94:8-95:8, 143:23-144:24; Kemp Report at 2-3).

[13] Even if Plaintiff claimed there was some delay in performing a colposcopy or biopsy as a result of Dr. Summerlin's ASC-US diagnosis—which they have not—there are no facts to support that any such delay caused any injury to Plaintiffs and thus there is no evidence sufficient to create a dispute of fact that would preclude granting summary judgment for Defendant. See Shadburn, 533 S.E.2d at 767.

[14] While we must assume that there was a violation of the standard of care by Dr. Summerlin, the Court notes that Dr. Rosenthal admitted that because the end result was the same, there was practically no breach in the standard of care by Dr. Summerlin. (Dep. of Dr. Rosenthal at 256:1-15).

treatment following the October 27, 2007, Pap smear was the same, Defendant's alleged violation of the standard of care did not delay the diagnosis or treatment of Adams' cervical cancer. See Zwiren, 578 S.E.2d at 865.

Because Plaintiffs cannot establish the element of causation, summary judgment is also granted on all claims involving a violation of the standard of care by Defendant's pathologist. Accordingly, Defendant's Motion for Summary Judgment is granted.[15]

III. CONCLUSION

For the foregoing reasons,

IT IS HEREBY ORDERED that Plaintiffs' Motion to Strike Declarations of Tiea L. Kesler [90] is **GRANTED**.

IT IS FURTHER ORDERED that Defendant's Motion to Strike Plaintiffs' Re-Designation of Martha Bishop Pitman, M.D. and Pitman Affidavit [92] is **GRANTED**.

[15] The Court finds that Plaintiffs' claim of loss of consortium is a derivative claim under Georgia law and is barred where summary judgment is granted on the main claims. See Briddle v. Cornerstone Lodge of Am., 654 S.E.2d 188, 189 (Ga. Ct. App. 2007); White v. Hubbard, 416 S.E.2d 568, 569-70 (Ga. Ct. App. 1992); Tomlinson v. Brogdon, No. 7:09-cv-11 (HL), 2010 WL 1529334, at *4 (M.D. Ga. Apr. 14, 2010); Robinson v. AirTran Airways, Inc., No. 1:09-CV-439-TWT, 2009 WL 3822947, at *3 (N.D. Ga. Nov. 13, 2009). The Court also finds that having granted summary judgment to Defendant on all claims, Plaintiffs' Motion to Exclude Testimony of Pathologist Regarding Standard of Care is moot.

IT IS FURTHER ORDERED that Plaintiffs' Request for Permission to File Supplemental Brief in Opposition to Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [96] is **DENIED**.

IT IS FURTHER ORDERED that Defendant's Motion for Leave to File Surreply in Further Support of Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [99] is **DENIED**.

IT IS FURTHER ORDERED that Defendant's Request to Take Judicial Notice [104] is **DENIED**.

IT IS FURTHER ORDERED that Defendant's Motion to Exclude Plaintiffs' Expert Dorothy Rosenthal, M.D. [74] is **GRANTED IN PART** and **DENIED IN PART**.

IT IS FURTHER ORDERED that Defendant's Motion for Summary Judgment [75] is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Testimony of Pathologist Regarding Standard of Care [73] is **MOOT**.

SO ORDERED this 3rd day of February, 2012.

WILLIAM S. DUFFEY, JR.
UNITED STATES DISTRICT JUDGE