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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 99-8053

D.C. Docket No. 93-CV-2051-RLV

CATHERINE "KIP" ALLISON,

Plaintiff-Appellant,

versus

McGHAN MEDICAL CORPORATION and
MINNESOTA MINING & MANUFACTURING
COMPANY (3M),

Defendants-Appellees.

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

(August 18, 1999)

Before COX, Circuit Judge, FAY, Senior Circuit Judge, and NANGLE*, Senior District Judge.

NANGLE, Senior District Judge:

*Honorable John F. Nangle, Senior U.S. District Judge for the Eastern District of Missouri, sitting by designation.

Catherine "Kip" Allison sought recovery in district court for injuries allegedly

suffered from breast implants manufactured by McGhan Medical Corporation and Minnesota Mining & Manufacturing Company ("3M/McGhan"). She asserted claims in negligence, fraud/misrepresentation and strict liability/failure to warn. After holding a three day Daubert hearing, the district court ruled inadmissible Allison's proffered expert testimony on causation. See Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). The district court granted summary judgment on the fraud/misrepresentation claims for failure to plead with particularity and to establish a prima facie case, and on the strict liability claim because Georgia's statute of repose had run. Because of Allison's inability to establish liability without the experts, the district court granted final summary judgment to 3M/McGhan on the remaining negligence and failure to warn claims. After careful but deferential review, we conclude that the district court's Daubert rulings were correct. Because the court properly excluded the expert testimony, we affirm its grant of summary judgment on the negligence claims. We additionally affirm summary judgment on Allison's other claims.

I. Background

In December 1979, at age 21, Kip Allison decided to get cosmetic silicone breast implants. She discussed her decision with her parents and a cousin who had implants. She also discussed the various associated risks of the implant surgery with

her plastic surgeon, Dr. Harvey Weiss, although the parties dispute the contents of this discussion. Dr. Weiss implanted a double lumen design,[1] manufactured by 3M/McGhan. After complications from the initial surgery developed, the left implant was replaced in December 1980 by a model also manufactured by 3M/McGhan. (Appellant's Br. at 3.)

In 1986 Allison was diagnosed with Hashimoto's thyroiditis (diffuse infiltration of the thyroid gland with white blood cells, resulting in diffuse goiter).[2] In 1987, Allison was diagnosed with Type I diabetes mellitus.[3] She also began experiencing debilitating fatigue, joint, muscle and nerve pain. In 1992 Dr. Bruce Bode, an endocrinologist, tested Allison for antinuclear antibodies and found that she had an extremely high titer of 1:5120.[4] Bode referred Allison to Dr. Sam Schatten, a

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[1]Double lumen implants have an inner silicone shell filled with silicone gel surrounded by an outer silicone shell that is filled with saline at the time of surgery.

[2]Stedman's Medical Dictionary 1812 (26th ed. 1995).

[3]Diabetes mellitus is a severe autoimmune disorder in which the body attacks the pancreas, eventually destroying insulin producing capacity. Type I diabetes cannot be "cured," but it can be managed by controlling blood sugar levels through diet and insulin injections. Uncontrolled diabetes can cause a host of serious, even fatal health problems. (Bode Dep. at 9-15.)

[4]Antinuclear antibodies (ANA) show an affinity for cell nuclei and are found in the serum of a high proportion of patients with systemic lupus erythematosus, rheumatoid arthritis, and certain collagen diseases, in some of their healthy relatives, and in about 1% of normal individuals. Stedman's at 100. Normal titers are less than 1:40 and then progress geometrically, i.e., 1:80, 1:160, 1:320 ad infinitum.

rheumatologist, who diagnosed her with Sjogren's syndrome[5] and fibromyalgia.[6] Dr. Schatten reported to Dr. Bode that he did not believe that Allison's breast implants were a source of her medical problems. (Appellees' Br. at 10-11.) Although Allison does not contend that her diabetes, thyroiditis, or neuropathies were caused or exacerbated by the implants, the parties dispute the degree of debilitation caused by Allison's diabetes, which 3M/McGhan alleges was severe. (Appellant's Reply Br. at 20; Appellees' Br. at 9-10, 14; see also Bode Dep. at 16, 22, 39-40 (describing Allison's diabetes as chronically poorly controlled, aggravated by bulimia, and contributing to her chronic fatigue); Schatten Dep. vol. I at 33 (describing onset of symptoms of daily temperature, fatigue, malaise and chills at age sixteen and arising from diabetes.))

Throughout 1992 Allison worsened, and although no one determined the cause of her ailments, she decided to have her implants removed at Dr. Bode's recommendation. (Bode Dep. at 60.) Dr. Philip Beegle, a plastic surgeon, performed the explantation surgery in February 1993. The pathology report stated that the outer shell of one implant was collapsed and the other contained minimal saline. Neither

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[5]Sjogren's causes dry eyes, dry mouth, with resulting temperature, fatigue, malaise, flu-like feeling and occasional chills. (R. 10, Schatten Dep. vol. I at 33-34, II at 40-41).

[6]"A disorder characterized by muscle pain, stiffness and easy fatigability. The cause is unknown and an estimated three million are affected in the U.S.A." The On-line Medical Dictionary (1997-98), <http://www.fibromyalgia.com>.

implant showed a loss of integrity of the inner lumen containing the silicone gel.[7] The implants were photographed and subsequently destroyed. After removal of the implants, Allison's non-diabetic symptoms improved. Her ANA levels steadily declined to a level of 1:80 in October 1997. Allison reported dramatic reduction of joint and muscle pain, and less fatigue. (Appellant's Br. at 5; Appellees' Br. at 8.) Dr. Schatten again evaluated Allison in 1993, shortly after the implants were removed. He did not change his former opinion, but advised Allison that she needed psychiatric help. (Id. at 11.)

Allison filed her complaint in September 1993 in the Northern District of Georgia seeking compensation for injuries allegedly caused by defectively manufactured breast implants. The case was transferred to the Northern District of Alabama as part of In re Silicone Gel Breast Implants Products Liability Litigation, 793 F. Supp. 1098 (J.P.M.L. 1992), before the Honorable Sam Pointer, Jr. for pretrial disposition in multidistrict proceedings. The case was later remanded to the Northern District of Georgia.

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[7]Although the pathologist made this initial assessment on gross examination, Allison asserts that the three pathologists who conducted microscopic examinations by reviewing slides of her breast tissue found silicone in the tissue "meaning, by definition, silicone had escaped from the gel lumen." (Appellant's Reply Br. at 14-15; see also R. 61, App. 42, Pathology Report; R. 37 Ex. A, Rule 26(a)(2) Disclosure Defs.' Expert Darryl Carter; R. 99, Shanklin Dep. vol. I at 122, 158-59.) 3M/McGhan's own expert pathologist, Dr. Darryl Carter, noted that on one side, "there are vacuoles with refractile non-birefringent material consistent with silicone but there is no associated inflammation. This is consistent with gel bleed." Id.

After remand, Allison stated orally to the court that she was proceeding on claims of strict liability, negligence, misrepresentation and fraud. To establish causation in the negligence claim, Allison proposed testimony from three physicians, Drs. Eric Gershwin, Douglas Shanklin and Sam Schatten. The district court, in accordance with the Supreme Court's mandate for federal judges to exercise gatekeeping functions to determine the reliability and relevance of scientific evidence, held a Daubert hearing. The court heard three days of evidence and argument from both sides and waded through literally volumes of paper of the documentary record on the science related to breast implants. After consideration of this evidence, the court granted 3M/McGhan's motions to exclude the expert causation witnesses on the basis that their testimony lacked reliability and relevance under Daubert. The court dismissed Allison's claims for local injuries and strict liability due to Georgia's ten year statute of repose.[8] The court additionally barred the claims for fraud/misrepresentation and failure to warn. Because causation is an essential element in the negligence claim, and Allison was unable to prove causation without the experts, the court subsequently granted final summary judgment to 3M/McGhan on all remaining claims. Allison appeals.

II. Standards of Review

[8]See discussion infra at note 17 regarding the district court's treatment of local injuries.

We review the district court's grants of partial summary judgment and summary judgment *de novo*, reviewing all facts and reasonable inferences in the light most favorable to the nonmoving party, and applying the same standard as the district court. Rodgers v. Singletary, 142 F.3d 1252, 1253 (11th Cir. 1998); Hale v. Tallapoosa County, 50 F.3d 1579, 1581 (11th Cir. 1995). A grant of summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "If the record presents factual issues, the court must not decide them; it must deny the motion and proceed to trial." Clemons v. Dougherty County, Ga., 684 F.2d 1365, 1369 (11th Cir. 1982). A grant of summary judgment may be upheld on any basis supported by the record. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1118 (11th Cir. 1993).

The Court reviews rulings on the admissibility of expert testimony for abuse of discretion. General Elec. Co. v. Joiner, 522 U.S. 136, 138-39 (1997). This deferential standard is not relaxed even though a ruling on the admissibility of expert evidence may be outcome-determinative. Id., 522 U.S. at 142-43. "Cases arise where it is very much a matter of discretion with the court whether to receive or exclude the evidence; but the appellate court will not reverse in such a case, unless the ruling is manifestly

erroneous." Id. (quoting Spring Co. v. Edgar, 99 U.S. 645 (1878)); see also N.V. Maatschappij Voor Industriele Waarden v. A.O. Smith Corp., 590 F.2d 415, 418 (1978) (pointing out that Rule 702, although broadening "the range of admissible expert testimony," does not alter the "manifestly erroneous" standard of review). The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence. Daubert, 509 U.S. at 592 n.10 (citing Bourjaily v. United States, 483 U.S. 171, 175-76 (1987)).

III. Analysis

A. Strict Liability/Failure to Warn

The district court properly granted summary judgment on the strict liability claims. The court found that the claims were barred under Georgia's ten year statute of repose which states:

> No action shall be commenced pursuant to this subsection with respect to an injury after ten years from the date of the first sale for use or consumption of the personal property causing or otherwise bringing about the injury.

O.C.G.A. § 51-1-11(b)(2). Subsection (c) provides an exception to the above:

> The limitation of paragraph (2) of subsection (b) of this Code section regarding bringing an action within ten years from the date of the first sale for use or consumption of personal property shall also apply to the commencement of an action claiming negligence of a manufacturer as the basis of liability, except an action seeking to recover from a

> manufacturer for injuries or damages arising out of the negligence of such manufacturer in manufacturing products which cause a disease or birth defect, or arising out of conduct which manifests a willful, reckless, or wanton disregard for life or property. Nothing contained in this subsection shall relieve a manufacturer from the duty to warn of a danger arising from use of a product once that danger becomes known to the manufacturer.

The district court found that the above language provides an exception to the statute of repose for negligence actions claiming failure to warn and disease causation, but does not create an exception for these theories under strict liability claims. Allison argues that her claim in strict liability/failure to warn should be allowed to stand because Georgia's Supreme Court found that "failure to warn causes of action [are] outside the ambit of the statue of repose . . . ." Chrysler Corp. v. Batten, 450 S.E.2d 208, 213 (Ga. 1994). Allison acknowledges, however, that the claim at issue in Batten was negligence rather than strict liability, but argues that "there is no good reason to believe the Court intended to differentiate between the two types of claims." (Appellant's Br. at 56.)

Allison's argument is unpersuasive because the Batten court had no reason to differentiate between negligence and strict liability actions when the action before it was only in negligence. Allison has failed to cite any Georgia cases in which a claim for strict liability/failure to warn was excepted from the statute of repose. Furthermore, Allison ignores the clear, unambiguous language of the statute which

exempts *only* negligence actions. While Allison may argue that it would have been logical for the legislature to have extended the exception to strict liability actions as well as negligence, it did not do so, and rewriting the statute is outside the purview of this or the district court. Accordingly, the district court correctly granted summary judgment barring Allison's strict liability claims.

B. Fraud/Misrepresentation Claims

The district court also correctly granted 3M/McGhan's motion for summary judgment on the fraud/misrepresentation claims. To maintain a cause of action for deceit or misrepresentation in Georgia, the injured plaintiff must show that defendant made a wilful or reckless misrepresentation of a material fact to induce another to act and upon which the other acts. O.C.G.A. § 51-6-2(a)-(b). Where the misrepresentation is wilfully made, privity is not necessary to give rise to the cause of action. O.C.G.A. § 51-6-2; Robert & Co. Assoc. v. Rhodes-Haverty Partnership, 300 S.E.2d 503, 504 (Ga. 1983); see also, Florida Rock & Tank Lines, Inc. v. Moore, 365 S.E.2d 836, 837 (Ga. 1988) (delineating circumstances allowing fraud claims when third parties have detrimentally relied). The district court found that Allison had failed to prove two essential elements, reliance and false representation.

Allison alleges that 3M/McGhan knew that its product lacked sufficient safety and efficacy data and that it, as well as the industry as a whole, knew that the

3M/McGhan double lumen implant had serious gel migrating problems. Additionally, she alleges that 3M/McGhan engaged in attempts to conceal negative facts about its products from the plastic surgery community, while at the same time stating in the package inserts that breast implants are "safe." (Appellant's Br. at 52-54.) Allison states that she was not informed of risks such as gel bleed, gel migration, inflammatory response, and systemic disease, and that she would not have consented to the surgery had she been informed of these risks. (Id. at 54-55.)

The district court found, and we agree, that Allison's allegations fail because she is unable to show any reliance on the alleged misrepresentations of 3M/McGhan. Allison conceded that she never had any contact with 3M/McGhan, but that she detrimentally relied on the assurances of her implanting surgeon, Weiss, who was in turn misled by 3M. The record does not support this allegation. Weiss gave undisputed testimony that he did not rely on information from implant manufacturers and their sales representatives. He stated that he maintained proficiency in breast implant surgery by consulting medical journals, attending medical conferences, and by conferring with other "well-qualified" colleagues. (Weiss Dep. at 7-8, 12-13.) Thus, Allison cannot sustain a cause of action under a theory of third party reliance as outlined in Florida Rock, 365 S.E.2d at 837, because she cannot show that 3M/McGhan fraudulently induced Weiss to act in some manner on which she relied.

Additionally, Allison cannot show direct detrimental reliance because she stated she never saw or read a package insert before her surgery. (Allison Dep. at 208-09.) The package insert itself does not describe the implants as "safe," but states that "[a]ugmentation mammoplasty is considered . . . to be one of the most satisfying procedures . . .," before describing the various risks, including capsular contracture and leakage. (Appellees' Br. at 67 (citing R. 61, App. 44.)) Because Allison was unable to show any direct or indirect detrimental reliance on representations by 3M/McGhan, her fraud/misrepresentation claims must fail, as the district court correctly found.

The district court dismissed the fraud count because Allison failed to plead with particularity as required by Federal Rule of Civil Procedure 9(b). The Eleventh Circuit has held that "[w]here a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with prejudice." Bank v. Pitt, 928 F.2d 1108, 1112 (11th Cir. 1991). Allison, upon remand to the district court, relied on the pleading in the "Amended Master Complaint" in the multidistrict proceedings which stated, "Defendants made misrepresentations to plaintiff that induced her to act to her detriment and are liable to her for their fraud." 3M/McGhan and other defendants filed a "Master Answer" that raised the insufficient particularity of the fraud

allegations as an affirmative defense. The transferee court, noting the shortcomings of the truncated fraud pleading, stated that "an amended . . . complaint . . . may be required before a case is scheduled for trial," but directed that "amendments prior to that time should generally be avoided." (Appellant's Br. at 50 (citing R. 61, App. 37.)) At no time did Allison amend her complaint. She now complains that the district court's summary judgment is an abuse of discretion because she merely followed the transferee court's instructions, that 3M/McGhan never sought a more definite statement, and that she should be given a renewed opportunity to plead under the doctrine of Bank.

The transferee court's order stated that an amended complaint *may* be required before a case is scheduled for trial. Certainly, when an opposing party has filed for summary judgment based on a failure to plead with particularity three weeks before the scheduled trial date, the time is ripe. Despite the instructions of the transferee court, litigants cannot cast on the district court the burden of prodding them into filing appropriate pleadings. 3M/McGhan clearly raised indefiniteness as an issue in its affirmative defense in its Master Answer adopted by the court. (Id. at n.17.) Thus, Allison's claim that 3M/McGhan never sought a more definite statement is contrary to the record.

Finally, Bank allows the plaintiff to make a more definite statement "[w]here

a more carefully drafted complaint might state a claim . . . ." 928 F.2d at 1112. Because Allison's bare bones fraud allegation requires the same proof of detrimental reliance as the misrepresentation claim, which she was unable to substantiate, the fraud claim must fail as well, regardless of any added particularity. Consequently, we find that the district court correctly granted summary judgment denying the fraud/misrepresentation claims.

C. Daubert Motions

The Court next examines the exclusion of Allison's expert witnesses. Allison submitted proposed testimony by three experts to prove causation. Dr. Eric Gershwin is a board certified immunologist, Dr. Douglas Shanklin is a board certified pathologist and Dr. Sam Schatten was Allison's treating board certified rheumatologist. Federal Rule 104(a) provides:

> Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination it is not bound by the rules of evidence except those with respect to privileges.

Under Rule 104(a) the parties submitted hundreds of scientific studies and journal articles for the district court to examine. In addition, accompanying affidavits and depositions were submitted and were before the court during the three day Daubert hearing. We note at the outset, despite 3M/McGhan's bandying about of terms such

as "junk science" and "science for hire," that the district court was careful to note the impeccable qualifications of the experts it was reviewing and that the court had before it sufficient record to adequately assess the Daubert issues. See City of Tuscaloosa v. Harcros Chem., Inc., 158 F.3d 548, 565 & n.21 (11th Cir. 1998) (finding an abuse of discretion when the court fails to conduct a suitable inquiry into the relevant factors to determine whether expert testimony should be admitted), reh'g denied, 172 F.3d 884 (11th Cir. 1999).

1. The Daubert Standard

The district court properly set out the standard enunciated in Daubert and its progeny, noting its interaction with other pertinent rules of evidence. Summarizing the applicable rules of admissibility of scientific evidence, this Court in City of Tuscaloosa, 158 F.3d at 562, stated that scientific expert testimony is admissible when

> (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusion is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

The Daubert analysis does not operate in a vacuum. Any proffer of scientific evidence is also subject to other rules of evidence. 3M/McGhan therefore challenged Allison's expert testimony on the basis of Rules 401, 402, 403, 702 and 703.

a. Rules 401, 402 and 403

Federal Rules 401 and 402 deal with the admissibility of relevant evidence. Rule 402 allows the admission of all relevant evidence "except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible." Rule 401 defines "relevant evidence" as that which has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."

3M/McGhan challenged the expert evidence on the basis of Rule 403 as well. While the district court only mentions this rule as one of the bases that 3M/McGhan offers for exclusion, it apparently indirectly entered the court's consideration. Rule 403 states, "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." The Supreme Court recognized in Daubert the intricate role of Rule 403 in an expert testimony admissibility analysis when it noted that expert testimony could be "both powerful and quite misleading because of the difficulty in evaluating it." 509 U.S. at 595 (quoting Weinstein, Rule 702 of the Federal Rules of Evidence is Sound; It Should Not Be Amended, 138 F.R.D 631

(1991)); see also Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1407 n.43 (D. Or. 1996) (finding a Rule 403 analysis applicable but unnecessary in making its decision to exclude testimony).

Thus, while Rules 401 and 402 reflect the general policy of the Federal Rules for liberal admission of evidence, Rule 403, working in conjunction with Rules 702 and 703, militates against this general policy by giving courts discretion to preclude expert testimony unless it passes more stringent standards of reliability and relevance. These stricter standards are necessary because of the potential impact on the jury of expert testimony. While the district court did not expressly exclude any testimony on the basis of Rule 403, we note that its consideration would only serve to buttress the court's ultimate exclusion of the proffered experts.

b. Rule 702 and Daubert's Requirements of Reliability and Relevance

Federal Rule of Evidence 702 states, "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." The Supreme Court imposed a special gatekeeping role on the trial judge in Daubert, 509 U.S. at 597, to ensure that scientific evidence is both reliable and relevant before being admitted as evidence. The Supreme Court later acknowledged

the difficulty of this role when it stated, "Neither the difficulty of the task nor any comparative lack of expertise can excuse the judge from exercising the 'gatekeeper' duties that the Federal Rules impose . . . ." Joiner, 522 U.S. at 148 (Breyer, J., concurring) (noting also that judges are not trained scientists). The Court opined that scientific knowledge is far afield from the normal expertise of judges and that they should proceed with caution lest they exceed their grasp. Daubert, 509 U.S. at 599 (Rehnquist, J., and Stevens, J., concurring in part and dissenting in part).

While meticulous Daubert inquiries may bring judges under criticism for donning white coats and making determinations that are outside their field of expertise, the Supreme Court has obviously deemed this less objectionable than dumping a barrage of questionable scientific evidence on a jury, who would likely be even less equipped than the judge to make reliability and relevance determinations and more likely than the judge to be awestruck by the expert's mystique. Also, a judge may enlist outside experts to assist in this sometimes very difficult decision. Using independent court-appointed experts may serve to quell the pseudo-scientist criticism.

Some judges, noting the general complexity of some expert evidence and in the penultimate exercise of caution and conscience, have exercised their inherent authority to use outside experts and have engaged in elaborate Daubert inquiries in an effort to

sort out conflicting scientific opinions in a comprehensive search for reliability and relevance. Judge Sam C. Pointer, the multidistrict transferee judge for federal breast implant cases, commissioned the National Science Panel ("NSP") under Rule 706 to consider the scientific evidence on whether silicone breast implants cause systemic disease. The NSP is considered a prototype investigative panel allowing the court to escape the heated rhetoric of the courtroom and obtain a more dispassioned analytical look at the scientific evidence with the assistance of neutral scientific experts.[9] United States District Judge Robert E. Jones in Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387 (D. Or. 1996), conducted an extensive Daubert hearing by using court-appointed technical advisors under Rule 104[10] to help evaluate the "reliability and relevance" of the scientific evidence in seventy cases brought against implant makers.[11] Because of

[9]The NSP in its initial report of December 1998 found no definitive scientific link between silicone breast implants and disease: "The most likely conclusion from these several analyses is that there is no meaningful or consistent association between breast implants or silicone gel-filled implants and any of the conditions studied." Betty A. Diamond et al., Silicone Breast Implants in Relation to Connective Tissue Diseases and Immunologic Dysfunction III-24 (1998) (R. 90, Ex. A). Depositions of the NSP members are ongoing. Courts with remanded cases were not required to await the final outcome of the panel findings, but could proceed to trial after conducting their own Daubert hearings as the district court did in this case. MDL-926 Order No. 31 at 6.

[10]Experts may be appointed under either FRE 104 or 706. FRE 706 requires the experts to act as additional witnesses, and they are subject to depositions and testifying at trial. Judge Jones appointed the experts under Rule 104 to keep them independent of ongoing proceedings. Hall, 947 F. Supp. at 1392 n.8.

[11]Judge Jones' ninety page opinion (including appendices) is remarkable in its depth of inquiry and clear exposition of the issues. It is worth reflective study by serious Daubert students. The scientists, selected from several scientific specialties, recommended that the testimony of the plaintiffs' experts be excluded from trial because the claim lacked scientific validity. Judge Jones,

the painstaking analyses which district courts undertake in making these admissibility determinations, their efforts are well deserving of the deference that the Supreme Court has accorded through the abuse of discretion standard enunciated in Joiner. While some courts on occasion use evidentiary findings of other courts as precedent when reviewing essentially the same factual issues in their Daubert decisions, the district court here did not use other breast implant causation precedents in making its decision. See Daubert, 43 F.3d at 1322 n.19 (noting on remand findings of other circuits denying admissibility of expert testimony on the issue of Bendectin causation of limb reduction). Nor do we depend on the conclusions of other courts regarding causation of systemic disease in breast implant recipients as precedent for affirming the decision of the district court. We merely note in passing that other courts, after thoroughly sifting through the scientific data, have come to the same decision, and indeed have even excluded some of the same experts as the district court did here in the execution of its gatekeeping role (an indication that the district court was not operating on the outer fringe of its discretion).

The gatekeeper role, however, is not intended to supplant the adversary system or the role of the jury: "[v]igorous cross-examination, presentation of contrary

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aligning himself with the opinions of his scientific advisors, agreed. While not required, he deferred the effective date of his decision pending the report of the NSP. The cases were subsequently settled before his opinion was officially adopted.

evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596. The judge's role is to keep unreliable and irrelevant information from the jury because of its inability to assist in factual determinations, its potential to create confusion, and its lack of probative value.

(1) The Reliability Prong

The Daubert Court listed four noninclusive factors courts should consider in determining reliability under Rule 702: (1) whether the theory or technique can be tested; (2) whether it has been subjected to peer review; (3) whether the technique has a high known or potential rate of error; and (4) whether the theory has attained general acceptance within the scientific community. Id., 509 U.S. at 593-94. Daubert's flexible four-pronged analysis supplanted the longstanding "austere" Frye standard which allowed the admission of expert testimony when it was generally accepted in the relevant scientific community. Frye v. United States, 293 F. 1013, 1013 (D.C. Cir. 1923). While Allison argues that the thrust of the Rules and of the Eleventh Circuit has been for liberal admissibility of evidence, she fails to appreciate the tempering qualities of Rules 403, 702 and 703 under Daubert and the fact that this Circuit has been twice overruled on Daubert decisions in precedent setting Supreme Court decisions in Joiner and Kumho Tire, both of which imposed stricter admissibility

standards than the Eleventh Circuit had deemed appropriate. Joiner, 522 U.S. 136; Kumho Tire Co. v. Carmichael, __ U.S.__, 119 S. Ct. 1167 (1999).

The district court, citing Daubert, properly recognized that the above four factors are not exhaustive and stated that its primary focus would "be solely on principles and methodology, not on the conclusions that they generate." Daubert, 509 U.S. at 595. Thus, the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 744 (3rd Cir. 1994). The Daubert court itself recognized that the factors it listed were a mere starting point for a court's analysis. Some other factors which this and other courts have considered in the Daubert analysis are reliance on anecdotal evidence (as in case reports), temporal proximity, and improper extrapolation (as in animal studies). Willert v. Ortho Pharm. Corp., 995 F. Supp. 979, 981-82 (D. Minn. 1998); National Bank of Commerce v. Dow Chem. Co., 965 F. Supp. 1490, 1504-05 (E.D. Ark. 1996).

(2) The Relevance Prong

Under the second prong of Daubert, the relevance requirement, the court must "ensure that the proposed expert testimony is 'relevant to the task at hand,' . . . i.e., that it logically advances a material aspect of the proposing party's case." Daubert,

43 F.3d at 1315 (on remand). Thus, the evidence must have a valid scientific connection to the disputed facts in the case. Daubert, 509 U.S. at 591 (holding "scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility"). This connection has been appropriately denominated as "fit." Id.

c. Rule 703

Finally, 3M/McGhan challenges Allison's expert testimony on the basis of Rule 703 which states:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

The Daubert Court pointed out that Rule 703 applies solely to expert opinions based on otherwise inadmissible hearsay. Id., 509 U.S. at 595. The Eleventh Circuit has alluded to another distinction to which some courts adhere, that Rule 702 governs only the scientist's "major premise" (the "principle, procedure, or explanatory theory derived by the inductive, scientific technique"), while Rule 703 addresses "the sources the expert may consult in collecting the case-specific information to serve as the minor premise." Davis v. Southern Bell Tel. & Tel. Co., (S.D. Fla. Feb. 1, 1994) (citing

Edward J. Imwinkelreid, The "Bases" of Expert Testimony: The Syllogistic Structure of Scientific Testimony, 67 N.C.L. Rev. 1 (1988)). Both rules are implicated in 3M/McGhan' motions.

The district court properly outlined the above standard in its opinion, and indeed, Allison does not dispute the court's delineation of the standard. Rather, Allison takes issue

with the district court's application of the standard to her proffered experts. The Court will therefore next examine whether the district court abused its discretion in applying this standard to Allison's three causation experts.

2. The testimony of Dr. Eric Gershwin

Dr. Gershwin proposed to testify that "silicone is capable of causing systemic harm in exposed women." (R. 62, Ex. 4, Gershwin Decl. at 3.) More specifically, "(a) silicone is not inert; (b) silicone can induce inflammation; (c) silicone can induce granulomas; (d) silicone migrates; (e) silicone implants can induce autoantibody production; (f) silicone is an adjuvant; (g) silicone can emulsify; and (h) agents which induce chronic inflammation and granulomas are associated with systemic complaints and disease." (Id. at 6.) Gershwin's ultimate conclusion was that in his opinion, "to a reasonable degree of medical certainty, . . . silicone breast implants cause or exacerbate systemic conditions in some women." (Id. at 22-23.) Gershwin stated the

bases of his opinion were his own research, clinical experience, peer reviewed literature on silicone as an adjuvant, the Marilyn Lightfoote study, studies examining silicone oil treatment of detached retinas, silicone related antibody studies, studies showing biomarkers in women with implants, case reports, and epidemiological (human statistical) studies.

The district court found that Gershwin's opinion was unreliable under Daubert because of improper scientific methodology, stating that Gershwin's theories had not been tested, were not subject to peer review and were not generally accepted by the scientific community. While we disagree with some of the district court's statements regarding peer review, we find it did not abuse its discretion in ruling Dr. Gershwins's testimony inadmissible.

The district court found that the five animal studies Gershwin relied on in addition to the Lightfoote study were inadequate to support the theory that silicone is an adjuvant. The court noted in passing that the Lightfoote unpublished study was not subjected to peer review. Allison establishes that Lightfoote's oral presentation was subject to the review of her peers. This fact, however, is no more helpful than peer review in other forums. As Allison and the Supreme Court point out, "Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability." Daubert, 509 U.S. at 593. Peer review

is significant under Daubert because "scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected." Id. But if peer review alone was dispositive, then the Frye standard of general acceptability in the scientific community would have remained adequate. Consequently, a finding that Lightfoote's animal study was peer reviewed does not mean it constituted an adequate basis for Gershwin's opinion that silicone breast implants cause systemic disease.

The court found Gershwin failed to explain the correlation of the results of Lightfoote's rat studies in which the rats were directly injected with silicone to symptoms in a human patient where the inner lumen of the implants had remained intact. Similarly, the court found that Gershwin failed to convincingly extrapolate data from the human retinal studies to cases involving unruptured implants. The court specifically noted extrapolation or "leap" problems with Gershwin's collagen antibody studies having a causal connection to systemic disease.

Daubert decisions in other courts warn against leaping from an accepted scientific premise to an unsupported one. Moore v. Ashland Chem. Inc., 151 F.3d 269, 278-79 (5th Cir. 1998) (citing Wheat v. Pfizer, Inc., 31 F.3d 340, 343 (5th Cir.1994) (finding that physician could not show reactive airways dysfunction syndrome ("RADS") was caused in a patient when his exposure level to toluene was

unknown)), cert. denied, 119 S. Ct. 1154 (1999); Braun v. Lorillard, Inc., 84 F.3d 230, 235 (7th Cir. 1996) (finding use of asbestos detection test for buildings improper for detection in human tissue); Daubert, 43 F.3d at 1319-20 (rejecting experts' opinions who relied on animal studies, chemical structure analyses, and epidemiological data when experts failed to clearly demonstrate scientific methodology); Conde v. Velsicol Chem. Corp., 24 F.3d 809, 814 (6th Cir. 1994) (finding animal studies inadequate for showing causation of disease in humans with chlordane exposure); Cavallo v. Star Enter., 892 F. Supp. 756, 769 (E.D. Va. 1995) (finding methodology of studies on toxic effects of chemicals sound but misapplied to the case at hand), rev'd in part on other grounds, 100 F.3d 1150 (4th Cir. 1996).

Allison complains that Dr. Gershwin did indeed explain the linkage between the rat studies and Ms. Allison's disease. (Appellant's Br. at 40-43.) While the district court noted the explanation, it was within its discretion to simply find it inadequate. Allison reasons that the adjuvancy papers

> were not published in the animal toxicology literature and were certainly not intended to provide information on how to treat arthritic rats; they were published in peer reviewed scientific journals intended to be read by clinicians and others treating real people[;] thus their relevance is established by the very books and journals in which they appeared.

(Id. at 43.) We are fully confident that the district court understood that these studies were not undertaken to treat silicone exposed rats. Publication in a peer reviewed

medical journal for humans, however, does not alone establish the necessary link required under Daubert. Cf. In re Paoli, 35 F.3d at 743 (explaining requirement for proper extrapolation from animal studies to show relevance). Furthermore, Allison does not explain why the results of these animal studies should trump more than twenty controlled epidemiological studies of breast implants in humans which have found no valid increased risk of autoimmune disease. See Conde, 24 F.3d 814 (finding fault with expert who neither testified to the collective view of his scientific discipline nor explained the grounds for his differences, citing Turpin v. Merrell Dow Pharm., Inc., 959 F.2d 1349, 1360 (6th Cir. 1992)).

Allison complains that the district court improperly rejected the retinal studies on the basis that no linkage was found with Allison's *unruptured* implants. Allison states that there was without dispute, silicone in Ms. Allison's breast tissue. Even assuming gel bleed, a finding that silicone *oil* emulsifies in the eye indicates that silicone gel similarly emulsifies in breast tissue and causes systemic disease is still quite a leap. As the Supreme Court pointed out in Joiner, 522 U.S. at 146-47, "[I]t was within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions" [of causation]. As in Joiner, the district court, after conducting a thorough review of the medical evidence, did not abuse its discretion by finding that

Dr. Gershwin failed to adequately establish the link between the animal, retinal, and anti-collagen studies and Allison's complaints of disease.

The district court next took a detailed look at the four epidemiological studies Gershwin offered to support his opinion but, in each case, the court found reasons why these studies did not supply an adequate foundation for Gershwin's causation opinion. Briefly, it found the Kayler[12] study unreliable because it was a re-analysis of other studies that had found no statistical correlation between silicone implants and disease. It found the Friis[13] study irrelevant because it specifically scrutinized muscular rheumatism, not systemic disease. Similarly, the Giltay[14] study found correlations between implants and increased risk of joint pain, a complaint which Allison did not have. While the study did support Allison's claim for burning eyes, the court noted that the women participating in the study were aware of the hypothesis, a factor which could have created bias, skewing the results and ultimately making its conclusions suspect. The court found that the Hennekens[15] study, which had the most significant

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[12]L.K. Kayler et al., Breast Implants Increase the Risk of Arthralgias: An Epidemiological Meta-Analysis, 43 J. Investigative Med. 129 (1995).

[13]S. Friis et al., Connective Tissue Disease and Other Rheumatic Conditions Following Breast Implants in Denmark, 39 Annals Plastic Surgery 1 (1997).

[14]Eric J. Giltay et al., Silicone Breast Prostheses and Rheumatic Symptoms: A Retrospective Follow-Up Study, 53 Annals Rheumatic Diseases 194 (1994).

[15]Charles H. Hennekens et al., Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals: A Retrospective Cohort Study, 275 JAMA 616 (1996).

statistical correlation of silicone and increased ANA, had a relative risk of only 1:24, a finding so significantly close to 1.0 that the court thought the study was not worth serious consideration for proving causation.[16]

The court found that Gershwin's proposed four studies were in direct contrast to over twenty other epidemiological studies which found no statistical correlation between silicone breast implants and systemic disease, strong evidence that a consensus exists in the general scientific community that no correlation exists. Allison complains that the district court erred by looking at *conclusions* rather than *methodology and principles* as Daubert directed. While weighing the relative findings of the studies may seem to be a resurrection of the Frye standard (general acceptance in the scientific community), courts have noted that Daubert's suggested criteria to examine whether the theory has attained general acceptance within the scientific community, Daubert, 509 U.S. at 593-94, does just that. Joiner made it clear that although principles and methodology were the focus, the court was not precluded from

[16]The threshold for concluding that an agent more likely than not caused a disease is 2.0. A relative risk of 1.0 means that the agent has no causative effect on incidence. A relative risk of 2.0 thus implies a 50% likelihood that the agent caused the disease. Risks greater than 2.0 permit an inference that the plaintiff's disease was more likely than not caused by the agent. Federal Judicial Center, Reference Manual on Scientific Evidence 168-69 (1994). Allison points out that the relative correlation of cigarette smoking to heart disease is only 1.5, and yet "[n]o one would seriously quarrel that smoking can cause heart disease." (Pl.'s Reply Br. at 5 n.6.) We note, however, that this risk is more that twice that found in the Hennekens study, and we do not think the district court abused its discretion in finding a 1.24 risk minimal in terms of causation. Moreover, showing *association* is far removed from proving *causation*.

looking at conclusions:

> [C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

Joiner, 522 U.S. at 146; see also Lust v. Merrell Dow Pharm., Inc., 89 F.3d 594, 598 (9th Cir. 1996) (noting that a court may properly scrutinize anomalous conclusions and reject expert opinion if the expert fails to identify and defend the reasons why his scientific methodologies yielded novel results). We find that the district court did not abuse its discretion by considering that the proffered conclusions in studies with questionable methodologies were out of sync with the conclusions in the overwhelming majority of the epidemiological studies presented to the court. We additionally note that the district court lists Allison's four problematic epidemiological studies as only one of many factors for ultimately rejecting Gershwin's testimony.

Allison states that because these studies were published in peer reviewed journals, then *ipso facto* their methodology has been determined sound. But as mentioned supra regarding the Lightfoote study, while peer review increases the likelihood that substantive flaws in methodology will be detected, scrutiny by one's peers does not insure admissibility. Again, it is well established that "[p]ublication

. . . is not a *sine qua non* of admissibility." Daubert, 509 U.S. at 593.

Allison complains that the district court failed to consider Gershwin's testimony that silicone can induce chronic inflammation, and chronic inflammation is associated with systemic disease. Allison states that Dr. Gershwin's opinion in this area is basic textbook medicine, is unassailable and was excluded *sub silentio* by the district court. While the district court did not specifically single out Gershwin's chronic inflammation theory for comment, we do not conclude that it failed to consider the testimony. The court's global conclusions regarding Dr. Gershwin's opinions, that they were untested and that extrapolations from animal studies were inadequate, is reasonable in light of Dr. Shanklin's testimony that "pathologists generally, as well as myself, are still learning the full implications of [chronic inflammatory problems]" and that no one to his knowledge had made the "connection" in the peer reviewed literature between silicone induced chronic inflammation and systemic disease. (Shanklin Dep. vol. I at 68-71.)

Allison also states that the district court should not have found Gershwin's reliance on case studies improper methodology. While we acknowledge the importance of anecdotal studies for raising questions and comparing clinicians' findings, in the face of controlled, population-based epidemiological studies which find otherwise, these case studies pale in comparison. See Hall, 947 F. Supp. at 1411

(finding that "case reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls"; hence, they do not supply scientific knowledge upon which an opinion can be based under Daubert); Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (finding case reports do not provide reliable scientific evidence of causation). The district court did not abuse its discretion by discounting Dr. Gershwin's reliance on case reports in the face of the overwhelming contrary epidemiological evidence presented.

While the court stated that Gershwin's studies had not been subjected to peer review, this factor has bare mention in the court's analysis of Gershwin's testimony. We find, in contrast to the district court, that many of Dr. Gershwin's *theories* had been subjected to peer review. Dr. Gershwin is a prolific scientific author and has published numerous articles in peer reviewed journals, and he himself is a peer reviewer. (R. 33, Pl.'s Submission of Expert Reports, Ex. 2.) However, the parties dispute to what extent his premise that breast implants cause systemic disease has been subjected to the relevant scientific community for review. (See Pl.'s Reply Br. at 20; Defs.' Br. at 49-51.) "Under the regime of Daubert . . . a district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 318 (7th Cir.1996). While we do not question the scientific expertise of Dr. Gershwin, we find the district court

correctly excluded his testimony on the individual and collective bases noted above. Even assuming that Dr. Gershwin's work had been subjected to the most rigorous scrutiny by the scientific community, this factor would not nullify the court's findings of unreliable foundation, inadequate extrapolation, the lack of human models and "fit." See Daubert, 509 U.S. at 591 ("'Fit' is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes."). Consequently, we find that the district court did not abuse its discretion in excluding Dr. Gershwin's testimony.

3. Testimony of Dr. Douglas Shanklin

Dr. Shanklin, a pathologist, proposed testimony regarding his conclusions after microscopic examination of Allison's tissue slides. (Pl.'s Resp. Defs.' Mot. Exclude Ev. at 197.) Dr. Shanklin would have testified that (1) a positive result to a "silicone sensitivity test" ("SST") is evidence that silicone causes disease; (2) chronic inflammation around a breast implant and granulomas found in breast capsule tissue trigger autoimmune process; (3) crystalline silica can be identified in breast tissue by a light microscope; and (4) crystalline silica in breast capsule tissue leads to autoimmune disease. The district court excluded Dr. Shanklin's opinions stating they

were based on unreliable methodologies.[17]

Allison complains that the district court rejected Shanklin's entire testimony on the basis of its rejection of his "silicone sensitivity test," which Shanklin did not intend to testify about because Allison had never had the test. Nevertheless, Allison defended the merits of the SST during the Daubert hearing (Daubert Hearing Proceedings Tr. vol. V at 13-20), even though she denied its applicability in her response to the Daubert motions. Because the SST was put in issue, the district court did not abuse its discretion by considering its reliability when evaluating Dr. Shanklin's proffered testimony.[18] But even if this test had not been a point of

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[17]While the Court might have entertained partial allowance of Shanklin's testimony as causation evidence of local injury, claims of local injury have been abandoned on this appeal. The parties dispute the actual ruling of the district court on whether chronic inflammation as a local injury was barred by the statute of limitations. Appellee's Br. at 4; Appellant's Reply Br. at 24. The Court need not address the lower court's ruling, however, because the matter is first mentioned in passing by Allison in her reply brief. Issues that are not clearly outlined in an appellant's initial brief are deemed abandoned. Federal Sav. & Loan Ins. Corp. v. Haralson, 813 F.2d 370, 373-74 n.3 (11th Cir. 1987); 9 Jeremy C. Moore et al., Moore's Federal Practice ¶ 228.01 (2d ed. 1985).

Allison's entire argument is that chronic inflammation is a cause of systemic disease. Oblique references to local injury in the initial brief are clearly inadequate to preserve the issue. See In re Trans World Airlines, Inc., 145 F.3d 124, 132-33 (3rd Cir. 1998) (finding broad and slight references inadequate to meet the substantive function of Fed. R. App. P. 28 requiring issues to be squarely addressed). Furthermore, this Court typically takes a dim view of second guessing the strategies of litigants, refusing to grant "relief they did not request, pursuant to legal theories they did not outline, based on facts they did not relate." Adler v. Duval County Sch. Bd., 112 F.3d 1475, 1481 n.12 (11th Cir. 1997), reh'g en banc denied, 120 F.3d 276 (11th Cir. 1997).

[18]Dr. Shanklin developed the test himself in conjunction with another physician. A positive SST is purportedly evidence of an immune response to silicone. The test's reliability has been called into serious question by other scientists. See V. Leroy Young, Testing the Test:

contention between the parties, we do not think it an abuse of discretion for the court to consider the general merits of an experts' work in the field in which he will be offering testimony, even if he will not be speaking specifically to each point the court scrutinizes. The district court pointed out that Dr. Shanklin's silicone sensitivity test was flawed because it used crystalline silica rather than silicone and that he had failed to produce any studies supporting his theory that silicone in the body breaks down to silica and then acts as an antigen. His silicone conversion hypothesis does not have support in the scientific literature.

Other evidence in the record which supports the district court's wholesale exclusion of Dr. Shanklin's testimony is that certain aspects of Allison's purported condition had not been documented through available medical tests. Allison complained of muscle pain or myalgia, yet this clinical state, defined by Allison's subjective complaints, was never verified by a muscle biopsy, so that a diagnosis of myositis, or inflammation of the muscles, was unsubstantiated.[19] (Shanklin Dep. vol. I at 74.) Therefore, Dr. Shanklin's comments regarding causation of Allison's

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An Analysis of the Reliability of the Silicone Sensitivity Test (SILS) in Detecting Immune-Mediated Responses to Silicone Breast Implants, 97 Plastic & Reconstructive Surgery 681 (1996) (discussing the general merits of the test; the test provided invalid results in six out of six individuals, indicating that it could not distinguish between persons with silicone breast implants and persons who never had silicone breast implants).

[19]The theory is that breakdown products from the implant get into muscle tissue causing direct chemical toxicity. (Shanklin Dep. at 117.)

myalgia have dubious weight.

Dr. Shanklin also indicated that his theories regarding chronic inflammation and systemic disease are in their infancy. In response to a question regarding whether chronic inflammation leads to multiple myositis, he could not confirm that it was established in the literature: "Many papers have small details which are not in the abstract. But the process is set up. The process is known to work as a matter of making the final connection, and that work is going on as we speak." (Id. at 78.) As noted supra, Dr. Shanklin testified that "pathologists generally, as well as myself, are still learning the full implications of [chronic inflammatory problems]," and to Dr. Shanklin's knowledge, no one had made this connection in peer reviewed literature. (Id. at 68-71.)

Dr. Shanklin was also questioned about silicone antibodies, cytokines,[20] and direct chemical toxicity, the mechanisms Shanklin stated led to the development of systemic disease in breast implanted women. (Id. at 118.) Dr. Shanklin emphatically stated that the mere presence of antibodies does not mean that a person will get sick

[20]Dr. Shanklin's theory is that chronic inflammation sets the stage for systemic disease–the affected cells release cytokines, which in turn lead to multiple myositis, a diagnosis that was not confirmed in Allison. (Shanklin Dep. vol. I at 88-89). Cytokines themselves indicate an activation of the immune mechanism. Because of their short half-life, they are very difficult to measure in humans. Although cytokines have been measured in some breast implanted women, this testing appears to be in its initial stages and therefore is not routinely performed at this time. (Id. at 91-93.) Hence, cytokine measurements were not done on Allison.

and that Allison had not been tested for any specific antibodies to silicone. (Id. at 140, 113.) When asked if he was aware that "the general consensus of the relevant scientific community has been that there is no antibody produced in response to silicone," Shanklin stated that "[t]he relevant community is just now beginning to weigh in on the subject." Furthermore, he stated that a group of scientists in Great Britain that had rejected his findings regarding immune responses were "simply wrong."[21] As to cytokines, he stated, "We are about to break into the dawning era of medicine by cytokine analysis. You are asking for data which won't be around for ten to fifteen years." (Id. at 96-97.) Regarding direct chemical toxicity, also referred to as silicone toxicity or siliconosis, Shanklin noted that it was "another mechanism which can be invoked about which little is known presently,"[22] even though he stated Allison had the disease. (Id. at 80.)

While Dr. Shanklin's theories may be proven in the future, and although he has

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[21]See Silicone Gel Breast Implants: The Report of the Independent Review Group (Jill Rogers Ass'n ed, July 1998) ("Following a careful consideration of the histopathological material provided by Professor Shanklin, the IRG did not agree with him that any of the changes seen constituted evidence of an immune response. In particular, neither vasculitis (inflammation of the blood vessels, indicative of immunological involvement) nor any other histological change suggesting an immune response could be seen in the tissues examined."). Id. at 19. (Shanklin Dep. vol. II, Ex. 11.)

[22]Shanklin remarked that he did not know whether Allison has "a supplemental direct chemical toxicity or not. Nobody has tested her for that, and very little is known from the research angle yet. That question won't be answered for another five to seven years." (Shanklin Dep. vol. I at 117-18).

strong beliefs regarding silicone related pathology, we find that his testimony is based more on personal opinion than on scientific knowledge.[23] In light of Dr. Shanklin's own admissions, we find that the district court did not abuse its discretion in finding that his testimony was unreliable,[24] was not generally accepted by the scientific community, and was unsupported by other studies. Allison simply does not prove the reliability of Dr. Shanklin's testimony by a preponderance of the evidence. Therefore, exclusion of Dr. Shanklin's testimony was not error.

4. Testimony of Dr. Sam Schatten

Dr. Schatten proposed to testify that the implants exacerbated Allison's fibromyalgia and Sjogren's syndrome, resulting in her fatigue. He would state that "there is a small subset of women with breast implants who become afflicted with rheumatological disease." (Pl.'s Resp. Defs.' Mot. Exclude Causation Test. at 206.) Additionally, he would testify that "there was a general consensus in the medical community with which he was familiar that breast implants caused disease in 'a

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[23]While scientific testimony need not be known to a certainty, Daubert does require that assertions be derived from "scientific knowledge." "Scientific" means proper grounding in the methods and procedures of science, or the "scientific method." "Knowledge" is more than subjective belief or unsupported speculation, but "applies to any body of known facts or to any body of ideas from such facts or accepted as truths on good grounds." Daubert, 509 U.S. at 589-90.

[24]As with Dr. Gershwin, the Court notes that Dr. Shanklin has published many articles in peer reviewed journals, yet this alone does not substantiate the scientific validity of his premise that Allison's silicone implants caused systemic disease.

percent of patients who have systemic rheumatic diseases.'" (Id.) Schatten recanted his former opinion, that he did not believe that Allison's breast implants were a source of her medical problems, which he formed when Allison consulted him shortly after the explantation surgery.

Schatten's revised opinion was made five years after the explantation surgery, on the basis of Allison's medical record and laboratory results and without benefit of a follow-up examination and after being approached by Allison's attorney. On the basis of information supplied by the attorney regarding the explantation surgery, the lowered ANA lab reports, and reported improvements in Allison's fibromyalgia and fatigue, Dr. Schatten stated that there was a possibility/probability[25] that "[Allison's] breast implants have played a role [in her symptomatic improvements], period." Schatten Dep. at 75. Allison contends that Schatten relied on information he gained by treating her, case reports and peer reviewed literature, as well as the information supplied by her lawyer. The district court rejected Schatten's testimony on the basis that Schatten's testimony was (1) inadmissible under Georgia law because he could testify only to a probability rather than a possibility of causation; (2) his testimony failed a Daubert analysis because it was tainted by reliance on unreliable sources; and

[25]In Schatten's deposition, he made approximately nine statements regarding the mere possibility of causation and exacerbation countered by one "probability" statement in response to a leading question by Allison's counsel.

(3) his conclusions were made in preparation for litigation.

Allison argues that the district court erred by excluding Dr. Schatten's testimony based upon its erroneous application of Georgia law at this stage of the proceedings and its erroneous finding that the testimony would be inadmissible under Georgia law. Because this action is based on diversity, Georgia substantive standards of law must apply. Erie Railroad Co. v. Tompkins, 304 U.S. 64 (1938). Proffered expert testimony must meet the legal as well as the substantive issues of the case. See In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1226 (D. Colo. 1998) (factoring in Colorado's standard of proof of "reasonable probability" in requiring a relative risk ratio above 2.0 for epidemiological causation); Daubert, 43 F.3d at 1320 (on remand) (considering substantive tort requirements under California law in assessment of whether expert evidence met Daubert's "fit" or helpfulness prong). The rule in Georgia is

> [i]n cases that involve issues of causation which, by the nature of the situation, can be resolved solely by expert medical evidence standing alone, . . . the evidence must naturally be based at least on reasonable probability. "It appears to be well settled that medical testimony as to the possibility of a causal relation between a given [negligent act] and the subsequent [injuries alleged to have been caused by the negligence] is not sufficient, standing alone, to establish such relation."

Maurer v. Chyatte, 326 S.E.2d 543, 545 (Ga. App. 1985) (citations omitted). Allison correctly states that the standard of proof in a civil case is preponderance of the

evidence and that "reasonable medical probability" is the functional equivalent of preponderance of the evidence. O.C.G.A. § 24-1-1; 24-4-3. Also, a plaintiff may present medical as well as non-medical evidence to show causation. Estate of Patterson v. Fulton-Dekalb Hosp. Auth., 505 S.E.2d 232, 236 (Ga. App. 1998). That breast implants can and did cause systemic disease in Allison is not a natural inference that a juror could make through human experience. McDaniel v. Employers Mut. Liab. Ins. Co., 121 S.E.2d 801, 804 (Ga. App. 1961). Thus, medical expert testimony was essential to prove causation in this case. Compare Georgia Cas. & Sur. Co. v. Jernigan, 305 S.E.2d 611, 616-17 (Ga. App. 1983) (refusing to strike expert's "possibility" opinion in its entirety because it was offered in conjunction with other non-expert evidence authorizing a finding of the requisite causal connection in the case).

Allison's causation evidence, however, consisted of testimony by three medical experts, two of which were already excluded in the court's opinion. Therefore, Schatten was more than a "piece of the puzzle." As the sole remaining causation expert, it was not error for the district court to consider Georgia's rule requiring statement of his opinion to a reasonable degree of medical or scientific certainty (or

by a preponderance of the evidence).[26] Failure to meet this burden means that the sole causation expert's opinion would not assist the trier of fact under Rule 702 because his degree of certainty would not be sufficient to establish probable cause and would thus be irrelevant.

Although Allison additionally argues that the court erred by applying summary judgment standards to exclude Dr. Schatten's testimony, we find this argument irrelevant considering the fact that no other causation experts remained.[27] Dr. Schatten's possibility testimony is not only excludable under Georgia law, but also falls short of the standards for proving medical causation under Daubert because of its lack of "fit." Consequently, the court did not abuse its discretion by excluding Dr. Schatten's testimony which was based on mere possibility of causation.

Additionally, the court found other independent grounds for excluding Dr. Schatten's opinions. The district court determined that Dr. Schatten's opinions were based on unreliable methodology. Dr. Schatten admitted that he had never tested his theory that implants exacerbate Sjogren's syndrome and that the scientific literature

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[26]Again, because local claims have been abandoned, supra n.17, the Court does not entertain an outcome premised on the possibility of partial allowance of Shanklin's testimony as it related to claims of local injury. Nevertheless, Schatten's testimony is excludable on two other grounds, as demonstrated infra.

[27]In Hall, 947 F. Supp. 1398 n.28, the court pointed out the distinctions of an admissibility inquiry under Rule 702 that considers a "more likely than not" state law standard and a sufficiency determination for summary judgment.

does not support his theory. (Schatten Dep. vol. I at 94-95; II at 103-04.) He also admitted that his exacerbation theory had never been peer reviewed and that the scientific literature, except for case reports, does not support a relationship of any kind between breast implants and Sjogren's syndrome or fibromyalgia. (Id. vol. I at 92; II at 29, 34.) Because the untested theories of Allison's experts are not generally accepted in the scientific community, they obviously have a high potential rate of error.

Finally, the court did not abuse its discretion by finding that Dr. Schatten's opinion was prepared in preparation for litigation. While Allison argues that Schatten's revised opinion was based on his examination, diagnosis and treatment of her supplemented by information developed since her last visit, it was within the district court's purview to determine that such an about face in Schatten's opinion occurred because the opinion was developed in preparation for litigation. Also, his reversal in opinion occurred without benefit of a follow-up examination.

The mere coincidence of temporality of the dropping ANAs and Allison's subjective reports of decreased fatigue after explantation are questionable bases for Dr. Schatten to reverse his prior opinion that was grounded on two clinical visits with his patient. See In re Breast Implant Litig., 11 F. Supp. 2d at 1232 (citing a string of cases finding that temporality is not evidence of causation); In re Paoli, 35 F.3d at 762

(finding self reports of symptoms in patients preparing for litigation unreliable when not verified by other means). While courts frequently find that expert testimony such as Dr. Schatten was planning to render is acceptable, even though it is solicited for litigation and well rewarded, we agree that the court did not abuse its discretion in scrutinizing the reversal of Schatten's former opinion and the grounds upon which it was reversed. We therefore find that it was within the district court's discretion to have excluded Dr. Schatten's testimony for any one of the three reasons it offered.

Courts have found that an abuse of discretion occurs when under Daubert the admissibility bar is too high. Ruiz-Troche v. Pepsi Cola., 161 F.3d 77, 85 (1st Cir. 1998). Defendants naturally favor strict admissibility standards, while plaintiffs argue for more liberal standards:

> Trial judges must exercise sound discretion as gatekeepers of expert testimony under Daubert. [Defendant], however, would elevate them to the role of St. Peter at the gates of heaven, performing a searching inquiry into the depth of an expert witness's soul--separating the saved from the damned. Such an inquiry would inexorably lead to evaluating witness credibility and weight of the evidence, the ageless role of the jury.

McCullock v. H.B. Fuller Co., 61 F.3d 1038, 1045 (2nd Cir. 1995). Striking the appropriate balance may sometimes be a difficult task. The Daubert remand court stated that the gatekeeping task was particularly daunting when the dispute, as in this case, "concerns matters at the very cutting edge of scientific research, where fact

meets theory and certainty dissolves into probability." Daubert, 43 F.3d at 1316. Despite the difficulty of this case, we find that the district court suitably exercised its discretion in excluding these experts; it found multiple grounds for their exclusion, and on each point its rationale was based on a careful evaluation of the record in light of the Daubert standards working in conjunction with other Federal Rules of Evidence. There was no error.

D. Summary Judgment on Remaining Negligence Claims

Finally, the district court did not err by granting summary judgment on the remaining negligence claims based on failure to warn and disease causation. As mentioned, supra, Georgia's ten year statute of repose created an exception for these claims. Because the court found Allison's causation testimony inadmissible, and such testimony was essential to maintaining the negligence claims, Allison was unable to assert a prima facie case. Therefore, summary judgment was proper.[28]

While other courts, such as Hall and In re Breast Implant Cases, 942 F. Supp 958 (E.&S.D.N.Y. 1996) postponed motions for summary judgment for their own reasons, we see no need for postponement in this case. As Daubert recognized,

> [s]cientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific

[28]As discussed supra in note 17, the Court will not consider whether it was error to grant final summary judgment on potential local injury claims because Allison abandoned those claims.

> project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment--often of great consequence--about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.

509 U.S. at 597. While we acknowledge that the debate regarding systemic disease and silicone products may be ongoing for years to come, we concur with the district court that final summary judgment is appropriate at this time and with these experts.

IV. Conclusion

We AFFIRM the district court's ruling for summary judgment for 3M/McGhan on the strict liability/failure to warn and fraud/misrepresentation claims. After careful but deferential review, we AFFIRM the district court's Daubert rulings excluding Allison's causation experts, finding that Allison has failed to show that the decision is manifestly erroneous. Because the court properly excluded the expert causation testimony, we AFFIRM its grant of final summary judgment to 3M/McGhan on the remaining negligence claims.