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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

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No. 09-13813

D.C. Docket No. 08-10052-CV-KMM

DOUGLAS C. KILPATRICK,

Plaintiff-Appellant,

versus

BREG, INC.,
a California Corporation
for profit,

Defendant-Appellee.

Appeal from the United States District Court
for the Southern District of Florida

(August 12, 2010)

Before BIRCH and MARCUS, Circuit Judges, and HODGES,* District Judge.

*Honorable Wm. Terrell Hodges, U. S. District Judge for the Middle District of Florida, sitting by designation.

HODGES, District Judge:

This is a negligence and products liability action involving the use of a pain pump manufactured by Breg, Inc. for use during and after surgery. The Plaintiff, Douglas Kilpatrick, claiming to have been injured by one of Breg's pumps, proffered a single expert witness on the issue of causation – Dr. Gary Poehling, M.D. The district court determined that the methodology used by Dr. Poehling to reach his conclusions was unreliable and, therefore, his testimony was inadmissible under Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993). Without the testimony of Dr. Poehling, the district court further determined that Kilpatrick could not establish the causation element in any of his claims, and final summary judgment was granted in favor of Breg.[1]

Kilpatrick appeals the exclusion of Dr. Poehling's testimony. Upon a review of the record and this Circuit's precedent establishing a highly deferential standard of review applicable to evidentiary determinations, we find that the district court did not abuse its discretion in excluding Dr. Poehling's testimony. We therefore affirm.

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[1]Kilpatrick conceded that absent the expert testimony of Dr. Poehling, summary judgment was proper.

I. Background Facts and Procedural History

On October 5, 2004, Kilpatrick underwent arthroscopic surgery on his right shoulder to repair a tear of his labrum, the ring of tissue that surrounds the shoulder socket, or glenoid. In an attempt to alleviate post-operative pain, Kilpatrick's surgeon inserted into Kilpatrick's shoulder joint a pain pump manufactured by Breg. The catheter of the pump was implanted intra-articularly (within the joint space). Over the next 48 hours, the pain pump delivered 120 cc's of the anesthetic .5% bupivacaine (trade name Marcaine) into Kilpatrick's shoulder.[2]

At the time of his surgery in 2004, Kilpatrick was 35 years of age and was a world class flats fishing guide in the Florida Keys. He returned to work for the 2005 fishing season. While working, Kilpatrick noticed some popping in his right shoulder, but felt better at the end of the season. During the 2006 season, Kilpatrick began to experience severe shoulder pain and limited motion while working. Kilpatrick returned to his surgeon who conducted additional testing and, in October 2006, diagnosed glenohumeral chondrolysis – a complete breakdown

[2]It is undisputed that Breg manufactured the pain pump but did not manufacture the bupivacaine.

of the cartilage in Kilpatrick's shoulder joint.[3] On November 13, 2006, another orthopedic surgeon performed a total shoulder replacement for Kilpatrick, and Kilpatrick claims that he will have to undergo several more such procedures during his lifetime.

On July 28, 2008, Kilpatrick filed a six-count complaint against Breg. Four of his claims assert theories of strict product liability for design defect, defect due to inadequate warning, defect due to nonconformance with representations, and defect due to failure to adequately test. Kilpatrick also asserted a negligence claim, and a claim for violation of the Florida Deceptive and Unfair Trade Practices Act, §§501.201-213, Florida Statutes. Kilpatrick alleges that, as a direct result of being administered bupivacaine using Breg's pain pump, he now suffers from debilitating shoulder pain and a permanent injury that has severely and negatively impacted his ability to work, resulting in economic harm including past and future medical expenses.

[3]The Parties agree that glenohumeral chondrolysis – the complete destruction of the cartilage of the shoulder joint – is a medical phenomenon that has emerged only recently, and that the first study suggesting its linkage with intra-articular pain catheters appeared as recently as 2006.

In April 2009, Kilpatrick disclosed Dr. Poehling as his sole expert on general and specific causation.[4] Dr. Poehling opined that the use of intra-articular pain pumps to dispense anesthetic directly to the shoulder joint can cause glenohumeral chondrolysis, and that the use of Breg's pain pump in this manner caused Kilpatrick's injuries. Following Dr. Poehling's deposition, Breg filed a motion to exclude his testimony, and a motion for summary judgment on the ground that Kilpatrick had not sufficiently demonstrated that Breg's pain pump could and did cause the type of injury Kilpatrick suffered.

On June 26, 2009, the district court granted Breg's motions and dismissed Kilpatrick's case with prejudice. The district court found that Dr. Poehling was qualified to testify as an expert,[5] but that his causation testimony was scientifically unreliable and therefore inadmissable under Fed. R. Evid. 702. In particular, the

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[4]In order to prevail on his products liability claims, Kilpatrick must offer proof of both general causation – that the device in question can cause harm of the type Kilpatrick alleges – and proof of specific causation – that the device in fact did cause Kilpatrick's injury. See McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1239 (11th Cir. 2005). To meet this burden requires the use of expert testimony.

[5]Dr. Poehling is an accomplished Board Certified orthopedic surgeon, author, professor, teacher, and lecturer. Since 1992 he has been the Editor In Chief of Arthroscopy – The Journal of Arthroscopic and Related Surgery, a major, peer-reviewed scientific publication. He has served as an advisory editor of the Shoulder Joint and Axilla section of Elsevier's Interactive Anatomy Journal, and was the Chairman of the Department of Orthopedic Surgery at the Bowman Gray School of Medicine at Wake Forest University from 1989 to 2007. There is no question that he was qualified to testify as an expert.

district court found after thorough discussion and analysis that: (1) the medical literature on which Dr. Poehling based his conclusions did not reliably support his general causation opinion; (2) Dr. Poehling did not reliably consider the true background risk for glenohumeral chondrolysis; (3) Dr. Poehling's concessions about the hypothetical and speculative nature of the medical science on the cause of chondrolysis "seriously undermine[d]" the reliability of his methodology; (4) Dr. Poehling's use of the "differential diagnosis" methodology to determine specific causation was flawed because it presumed the existence of general causation; and (5) Dr. Poehling's opinion on specific causation was improperly based solely on a temporal relationship between the use of Breg's pain pump and Kilpatrick's injuries.

On July 15, 2009, the district court entered final judgment in favor of Breg. This appeal followed.

II. Standard of Review

This Court reviews a trial court's decision to exclude an expert's testimony pursuant to Daubert under an abuse of discretion standard. General Elec. Co. v. Joiner, 522 U.S. 136, 140 (1997); McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1238 (11th Cir. 2005); Rink v. Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005). "This standard of review requires that we defer to the district court's

ruling unless it is 'manifestly erroneous.'" Rink, 400 F.3d at 1291 (quoting Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1340 (11th Cir. 2003)). "Because the task of evaluating the reliability of expert testimony is uniquely entrusted to the district court under Daubert . . . we give the district court 'considerable leeway' in the execution of its duty." Id. (quoting Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999)). This deferential standard is not relaxed even though a ruling on the admissibility of expert evidence may be outcome determinative. Joiner, 522 U.S. at 142-43.

In addition, we note that "[t]he burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1256 (11th Cir. 2002) (quoting Allison v. McGhan Med. Corp., 184 F.3d 1300, 1306 (11th Cir. 1999)).

III. The Daubert Standard

Daubert requires that trial courts act as "gatekeepers" to ensure that speculative, unreliable expert testimony does not reach the jury. 589 U.S. at 597, n. 7. The trial court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the

same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho, 526 U.S. at 152.

Federal Rule of Evidence 702 governs the admission of expert testimony in federal court, and provides that:

> 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.

Applying these principles, this Court has previously held that expert testimony may be admitted if three requirements are met. First, the expert must be qualified to testify competently regarding the matter he or she intends to address. Second, the methodology used must be reliable as determined by a Daubert inquiry. Third, the testimony must assist the trier of fact through the application of expertise to understand the evidence or determine a fact in issue. Tuscaloosa v. Harcros Chemicals, Inc., 158 F.3d 548, 562 (11th Cir. 1988).

This case hinges on whether the methodology used by Dr. Poehling was reliable under Daubert. In deciding the question of reliability, the Supreme Court articulated a non-exhaustive list of relevant factors to consider: (1) whether the

expert's theory can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether the technique is generally accepted in the scientific community. Daubert, 509 U.S. at 593-94; McCorvey, 298 F.3d at 1256. The court must do "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 593-94.

IV. Dr. Poehling's Testimony

Kilpatrick first argues that the district court improperly focused on Dr. Poehling's conclusions instead of his methodology. This argument is simply without merit; even a cursory review of the district court's lengthy and detailed decision refutes the claim.[6] The district court focused exclusively on the materials and methods Dr. Poehling used to form his opinions (*i.e.* his methodology). This is exactly what the district court was supposed to do.

Kilpatrick next contends that because the methods Dr. Poehling used to reach his conclusions (reviewing medical literature and the "differential diagnosis"

[6]See Kilpatrick v. Breg, Inc., No. 08-10052-CIV, 2009 WL 2058384 (S.D. Fla. Jun. 25, 2009).

methodology)[7] were not new or novel, the district court should have refrained from assessing the reliability of these methods and should have focused solely on whether Dr. Poehling was qualified to testify as an expert – testimony that would have been helpful to the jury. Such an approach goes against the law of this Circuit, which has reversed trial courts who abdicate their gatekeeper role and refuse to assess reliability. See McClain, 401 F.3d at 1238. To be sure, there are instances in which a district court may determine the reliability prong under Daubert based primarily upon an expert's experience and general knowledge in the field, e.g., United States v. Brown, 415 F.3d 1257 (11th Cir. 2005); 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. See Kumho Tire, 526 U.S. at 149 ("We conclude that Daubert's general principles apply to the expert matters described in Rule 702. The Rule, in respect to all such matters, establishes a standard of evidentiary reliability."); see also Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1197 (11th Cir. 2002) (noting that the Supreme Court in Kumho "made it clear that testimony based solely on the experience of an expert would not be admissible.").

[7]The "differential diagnosis" methodology "is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999).

Dr. Poehling testified that he formed his opinions after reviewing medical literature and applying the differential diagnosis method. Thus, it was entirely proper – indeed necessary – for the district court to focus on the reliability of these sources and methods. To hold otherwise would encourage trial courts to simply rubber stamp the opinions of expert witnesses once they are determined to be an expert. See Allison v. McGhan Medical Corp., 184 F.3d 1300, 1316-17 (11th Cir. 1999) ("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.").

A. General Causation Testimony

Dr. Poehling testified at his deposition that the use of pain pumps to administer bupivacaine intra-articularly can cause glenohumeral chondrolysis. In reaching this conclusion, Dr. Poehling admitted that he did not conduct any tests himself, and did not rely on any epidemiological studies of human beings that connect intra-articular pain pumps or the use of bupivacaine with glenohumeral chondrolysis.[8] The absence of such evidence is not fatal, but makes his task to show general causation more difficult. See Rider, 295 F.3d at 1198-99. In

[8]"Epidemiology, a field that concerns itself with finding the causal nexus between external factors and disease, is generally considered to be the best evidence of causation in toxic tort actions." Rider, 295 F.3d at 1198.

particular, the basic methodology employed to reach the conclusions must be reliable and sound. Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 745 (11th Cir. 1986) (citing Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1535-36 (D.C. Cir. 1984)).[9]

Dr. Poehling reviewed five sources to make his general causation assessment. All of the sources are articles from various medical journals, none of which were based on epidemiological studies. The district court considered four of these items of literature both separately and in combination, and found them insufficient to satisfy the reliability requirement of Fed. R. Evid. 702.

The district court began by looking at the articles in combination and noted that only one of the articles was a comparative study of humans who had undergone arthroscopic surgery involving pain pumps. None of the articles explained the mechanism by which bupivacaine damages cartilage, and none of them offered an ultimate conclusion as to the general causation of glenohumeral chondrolysis in humans. A review of these articles confirms the district court's findings, and Kilpatrick does not dispute them.

[9]Kilpatrick's argument that conducting any epidemiological studies would be unethical, because it would require the potential destruction of a person's shoulder cartilage, has some merit. But in the absence of such studies, the nature of the other evidence (case reports, animal studies, in vitro studies) becomes that much more important, and the court's consideration of such evidence and the methodologies used must be that much more searching.

1. The Hansen Study

The district court first considered a 2007 article from the American Journal of Sports Medicine (the "Hansen study").[10] The Hansen study analyzed the medical records of 152 patients who had undergone 177 arthroscopic shoulder surgeries. Of these 152 patients, only nineteen shoulders in seventeen patients had bupivacaine-dispensing pain pumps inserted into them, and of those, only twelve shoulders in ten patients developed chondrolysis. According to Dr. Poehling, this 63% (twelve out of nineteen shoulders) incidence of chondrolysis was the "strongest" evidence of a connection between intra-articular pain pumps and chondrolysis.

The district court concluded that the Hansen study was unreliable because it did not include any statistical analysis and did not explain whether it was statistically meaningful to extrapolate from such a small sample size. The study also did not account for other causes of chondrolysis – specifically noting that "[i]t is likely that other unrecognized factors are also involved. . . . [and that other factors] may have played a role not yet completely understood at this time." The study also failed to explain why seven of the patients (almost 40%) treated with

[10]Brent P. Hansen *et al.*, Postarthroscopic Glenohumeral Chondrolysis, 35 Am. J. Sports Med. 1628-34 (July 2007). The Hansen study was first presented in 2006 to the American Academy of Orthopedic Surgery.

pain pumps did not develop chondrolysis – a result that Dr. Poehling himself could not explain. More importantly, the study did not reach a conclusion as to the general causation of chondrolysis, stating that "[n]o etiology [of chondrolysis] has been firmly identified . . ." and that further research was needed. All that the authors were able to state was that pain pumps eluting Marcaine "appear highly associated with post-arthroscopic glenohumeral chondrolysis."

In sum, the Hansen study was merely a compilation of case reports without any statistical context. Such studies "lack control[] and thus do not provide as much information as controlled epidemiological studies do . . . Causal attribution based on case studies must be regarded with caution." McClain, 401 F.3d at 1253 (internal citations omitted). See also Rider, 295 F.3d at 1199 ("[W]hile they may support other proof of causation, case reports alone ordinarily cannot prove causation.").

Faced with a study that failed to explain why 40% of patients treated with intra-articular pain pumps did not develop chondrolysis, the lack of any statistical analysis discussing the relative importance of this study, the failure to account for other causes of chondrolysis, and the omission of any conclusion on general causation, the district court did not abuse its discretion in finding that the Hansen study was not a source upon which Dr. Poehling could reasonably rely under Fed.

R. Evid. 702. Kilpatrick's focus on the authors' description of an "association" between pain pumps and glenohumeral chondrolysis is unavailing. "[S]howing [an] association is far removed from proving causation." Allison, 184 F.3d at 1315 n. 16 (emphasis in original).

2. The Gomoll Study

The district court next considered a 2006 article discussing a controlled study of rabbits (the "Gomoll study").[11] The authors of this study administered Marcaine to live rabbits continuously through a catheter over 48 hours, while other rabbits received saline over the same time period. The animals were euthanized one week later and their cartilage was examined.

The authors of the Gomoll study concluded that "[c]ontinuous intra-articular infusion of bupivacaine (Marcaine), with and without epinephrine, led to significant histopathologic and metabolic changes in articular cartilage." However, the authors were careful to limit this conclusion to rabbits, and did not extrapolate their findings to humans, noting that further study was warranted:

> One limitation of our study, which it shares with most animal models, should be considered; although we were able to show the detrimental effects of bupivacaine on

[11] Andres Gomoll *et al.*, Chondrolysis After Continuous Intra-Articular Bupivacaine Infusion: An Experimental Model Investigating Chondrotoxicity in the Rabbit Shoulder, 22 Arthroscopy 813-19 (August 2006).

> the cellular and tissue level in a rabbit model, it remains to be determined whether human cartilage is equally susceptible and whether these histopathologic and functional changes result in the subsequent development of rapidly progressive osteoarthritis . . . . Because epidemiologic study of chondrolysis in humans will require an extremely large sample size because of the low incidence and prevalence of this condition, additional studies in larger animal model with longer-term follow-up, as well as in vitro studies with continuous exposure of human cartilage to bupivicaine, are necessary to provide further understanding.

Thus, by its own words, the Gomoll study at most suggests a connection between the use of intra-articular pain pumps, bupivacaine, and chondrolysis in rabbit cartilage. This does not equate to a conclusion of direct causation (or a connection of any degree) between the use of such pain pumps and chondrolysis in humans.

The authors of the Gomoll study further acknowledged that "no data exists regarding the human-equivalent dosing of intra-articular bupivacaine in a rabbit shoulder model. . . ." Dr. Poehling also could not explain the possible differences in dose-response relationship between humans and rabbits. As the district court correctly noted, a dose-response relationship is "the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." McClain, 401 F.3d at 1242 (citing David Eaton, Scientific Judgment and Toxic Torts: A Primer in Toxicology for Judges and Lawyers, 12 J. L. & Pol'y 1,

11 (2003)).[12] The lack of any data or any explanation by Dr. Poehling on this point puts the methodology of both the Gomoll study, and Dr. Poehling's general causation opinions in question. "The expert who avoids or neglects [the dose-response] principle of toxic torts without justification casts suspicion on the reliability of his methodology." McClain, 401 F.3d at 1242.

The district court did not abuse its discretion in finding the Gomoll study unreliable under Fed. R. Evid. 702. See Joiner, 522 U.S. at 144-45 (finding no abuse of discretion where the trial court rejected an expert's reliance on animal studies that were dissimilar to the facts of the case).

3. The Greis Report

The third article the district court addressed was a 2008 case study of two teenage female swimmers who underwent arthroscopic surgery and subsequently developed chondrolysis (the "Greis report").[13] Both patients received bupivacaine using intra-articular pain pumps following surgery. The district court found this study to be unreliable for two reasons. First, the study only analyzed these two patients' specific cases – there was no statistical analysis and the study did not

[12]Dose-response relationship is "[a] relationship in which a change in amount, intensity, or duration of exposure to an agent is associated with a change – either an increase or decrease – in risk of disease." McClain, 401 F.3d at 1242-42 (citations omitted).

[13]Patrick Greis *et al.*, Bilateral Shoulder Chondrolysis Following Arthroscopy: A Report of Two Cases, 90 J. Bone & Joint Surgery 1338-44 (June 2008).

draw any medically valid conclusions. The district court's decision comports with the law of this Circuit. McClain, 401 F.3d at 1254 ("case reports raise questions; they do not answer them."); Rider, 295 F.3d at 1199 ("courts must consider that case reports are merely accounts of medical events. They reflect only reported data, not scientific methodology."). Indeed, Dr. Poehling himself acknowledged that case reports such as the Greis report are "way down at the very bottom as far as medical strength of an article" and cannot establish medical causation.

The district court also found fault with placing reliance upon the Greis report because it expressly recognized that "the exact cause of the chondrolysis remains unknown" and listed a multitude of factors that could have caused these patients' chondrolysis. The report went on to hypothesize about the various factors, without drawing any conclusions. As a result, the district court found that Dr. Poehling's dependence upon an anecdotal case report to conclude that intra-articular pain pumps administering bupivacaine generally causes chondrolysis could not satisfy the reliability standards of Fed. R. Evid. 702. The court finds no error in this determination.

4. The Lubowitz Editorial

Lastly, the district court considered a one-page editorial that Dr. Poehling co-authored with Dr. James Lubowitz (the "Lubowitz editorial") in 2007.[14] The editorial is not a case report or study but, as Dr. Poehling admitted "is general in nature and does not present any factual context that would allow the court to discern its relevance to this case." The very title of the editorial states the need for further research.

With respect to the causes of glenohumeral chondrolysis, the Lubowitz editorial stated that "[t]he etiology of glenohumeral chondrolysis may be multifactorial. Future research is required to determine the cause, and proper prevention, of shoulder chondrolysis." Dr. Poehling admitted that this statement remained correct two years later at the time of his deposition. The editorial also recognized the existence of chondrolysis caused by unknown factors – "idiopathic" chondrolysis. As Dr. Poehling himself admitted, this editorial is clearly inadequate as a basis for a scientific judgment about the general causation of chondrolysis.

[14]James Lubowitz & Gary Poehling, Editorial: Glenohumeral Thermal Capsulorrhaphy Is Not Recommended – Shoulder Chondrolysis Requires Additional Research, 23 Arthroscopy 687 (July 2007).

5. The District Court's Conclusion

The district court exercised its discretion and found that each of these articles, both taken together and separately, were not sufficiently reliable to support Dr. Poehling's opinion on general causation. Kilpatrick challenges the district court's findings with respect to this literature on several grounds. First, Kilpatrick claims that the articles do in fact establish a direct causal link between the use of intra-articular pain pumps to dispense bupivacaine and chondrolysis. As the district court concluded, however, this argument is belied both by the plain language of the articles and by Dr. Poehling's own testimony that none of the articles he relied upon – indeed no literature in existence at the time of his deposition – establishes such a direct causal link. Dr. Poehling's admission that the literature is speculative in nature is by itself sufficient to warrant a finding of unreliability.

Second, Kilpatrick lists seven additional articles and studies that he contends Dr. Poehling relied upon in reaching his conclusions, and which the district court wrongfully failed to take into account. According to Kilpatrick, these other articles conclusively establish a direct causal link between the use of intra-articular pain pumps, bupivacaine, and chondrolysis. On this point, Kilpatrick is partially correct – a review of Dr. Poehling's deposition testimony

shows that he mentioned one additional article – a January 2008 study of cow and human cartilage by Dr. Constance Chu and others (the "Chu study").[15] However, this study suffers from the same deficiencies as the Gomoll study – the authors of the Chu study noted that their "in vitro assessments do not account for dilutional effects or in vivo reparative processes."[16] The Chu study went on to state that "in vitro results cannot be directly extrapolated to clinical practice" and concluded that "the in vitro bovine chondrocyte data . . . support the need for comprehensive additional studies." In other words, the authors could not state how their test results would transfer when conducted on a live human subject.

Thus, even if the district court had considered the Chu study together with the other four pieces of literature it examined, it is clear that the court would not have altered its conclusion. See Allison, 184 F.3d at 1313-14 (affirming exclusion of causation testimony based upon animal studies because the expert "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."). One additional animal study discussing the differences between in vitro and in vivo

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[15]Constance Chu, *et al.*, The In Vitro Effects of Bupivacaine on Articular Chondrocytes, 90 J. Bone & Joint Surg. 814, 820 (Jan. 2008).

[16]"In vitro" refers to procedures performed in a controlled environment, such as a test tube or petri dish. "In vivo" studies refers to experiments using an entire, living organism, such as a live human subject.

results, and the need for further studies does not come close to satisfying Rule 702's reliability requirements, and does not establish an abuse of discretion on the part of the district court.[17]

The other six articles Kilpatrick lists in his brief are nowhere mentioned in Dr. Poehling's deposition testimony despite extensive and repeated requests by Breg's counsel exhorting Dr. Poehling to identify every single article and study he relied upon. Instead, Kilpatrick points to a statement by Dr. Poehling at his deposition that he considered various other articles which were on his computer at home. Such a vague reference to other unnamed articles is not sufficient to support Dr. Poehling's conclusion on general causation, and does not render his methodology reliable. Dr. Poehling had ample opportunity to identify all of the bases for his conclusions and to explain his methodology in reaching those conclusions. It was not an abuse of discretion for the district court to ignore allusions to other articles.

Last, Kilpatrick argues that the district court erred when it considered each identified piece of literature separately, rather than in combination. First, it is

[17]While the district court did not specifically identify the Chu study in its order, the trial court did state that it reviewed the entire voluminous record in this case, including Dr. Poehling's expert report, his deposition testimony, and the medical literature upon which he based his opinions. Thus, it is not entirely clear that the district court ignored the Chu study, and in any event, the district court did not abuse its discretion.

clear that the district court did consider all of the articles together, and specifically considered Dr. Poehling's own admission that no literature exists concluding that intra-articular pain pumps are the cause of glenohymeral chondrolysis. Rather, all of the articles merely stated potential associations and speculated that such pain pumps medically cause glenohumeral chondrolysis. The district court also noted that none of the articles explained the mechanism by which bupivacaine damaged human cartilage. The fact that the district court then further analyzed each article in detail and found each to be unreliable was a proper approach to the issue. See Joiner, 522 U.S. at 145-46.

In summary, the district court did not abuse its discretion in finding that the literature Dr. Poehling based his conclusions upon was insufficient to create a reliable methodology which passes Daubert muster. See McClain, 401 F.3d at 1245 ("[t]he Daubert requirement that the expert testify to scientific knowledge – conclusions supported by good grounds for each step in the analysis – means that any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible.") (internal citations and quotations omitted).[18]

[18]The court does not intend to suggest that in order to survive Daubert review, a methodology based on a review of existing literature on the subject must rely on articles that draw a direct, concrete, and absolute causal connection. However, in this case, given the paucity of reliable evidence and the speculative nature of the articles Dr. Poehling relied upon, the court cannot disagree to the point of finding an abuse of discretion in the district court's conclusion (continued...)

6. Background Risk

The district court was further persuaded by the fact that none of the articles took into account the background risks for chondrolysis: "[t]he risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges without exposure to the drug or chemical in question." McClain, 401 F.3d at 1243 (emphasis in original). Several of the articles Dr. Poehling relied upon expressly noted that the cause of chondrolysis remains unknown, and that idiopathic causes could play a factor. Dr. Poehling ignored such background risks. While recognizing the existence of idiopathic (or unknown) causes of chondrolysis, he dismissed them by merely stating that the risk of idiopathic chondrolysis is essentially zero. The failure to take into account the potential for idiopathically occurring chondrolysis – particularly when glenohumeral chondrolysis is a relatively new phenomenon in need of further study – placed the reliability of Dr. Poehling's conclusions in further doubt. McClain, 401 F.3d at 1243-44 ("A reliable methodology should take into account the background risk.").

[18](...continued)
that Dr. Poehling's methodology on general causation was not reliable for purposes of Rule 702.

B. Specific Causation Testimony

Dr. Poehling also opined that the continuous intra-articular infusion of bupivacaine through Breg's pain pump caused Kilpatrick's chondrolysis. When asked the basis for this conclusion, Dr. Poehling could point to nothing other than the literature and the temporal relationship between Kilpatrick's initial surgery and his chondrolysis.

> . . . I think any scientist would sit down and look at this case and observe the factors of what happened to this patient, what he looked like before and what he looks like now would come to the conclusion that bipuvacaine is what caused it, and I don't think that that's just me or — I think any real scientist.

Such specific causation testimony has been found to be inherently unreliable in this Circuit. McClain, 401 F.3d at 1254 ("[T]he temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation. It is also subject to the problem of assuming what the witness is trying to prove.").

Dr. Poehling testified that he used the "differential diagnosis" methodology to find specific causation. This method involves a process of compiling, or ruling in, a comprehensive list of possible causes that are generally capable of causing the illness or disease at issue, and then systematically and scientifically ruling out

specific causes until a final, suspected cause remains. McClain, 401 F.3d at 1253. It assumes the existence of general causation, and focuses instead on specific causation. The expert must show through reliable evidence that the remaining cause ruled in as actually being capable of causing the condition.

Kilpatrick is correct that differential diagnosis itself has been recognized as a valid and reliable methodology. But that is not the issue about which the district court found fault. Rather, the district court found that Dr. Poehling's application of this methodology was flawed. In order to correctly apply this methodology, Dr. Poehling must have complied a comprehensive list of potential causes of Kilpatrick's injury and must have explained why potential alternative causes were ruled out. However, Dr. Poehling only ruled out two causes – thermal energy and gentian violet contrast dye. He clearly testified that he could not explain why potentially unknown, or idiopathic alternative causes were not ruled out. Dr. Poehling also admitted that neither he nor anyone else in the medical community "understands the physiological process by which [chondrolysis] develops and what factors cause the process to occur." Thus, the key foundation for applying differential diagnosis was missing, and based on these deficiencies, the district court found that Dr. Poehling failed to apply the differential diagnosis methodology reliably. The district court did not abuse its discretion in so

concluding. McClain, 401 F.3d at 1253 (an "expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on the patient.").

Kilpatrick cannot overcome the fact that Dr. Poehling's specific causation testimony is rooted in a temporal relationship. "[P]roving a temporal relationship . . . does not establish a causal relationship . . . . [S]imply because a person takes drugs and then suffers an injury does not show causation." McClain, 401 F.3d at 1243 (emphasis in original). This is a classic "post hoc ergo propter hoc" fallacy which "assumes causation from temporal sequence. It literally means 'after that, because of this' . . . . It is called a fallacy because it makes an assumption based on the false inference that a temporal relationship proves a causal relationship." Id. Dr. Poehling made clear that he reached his conclusions with respect to Kilpatrick's injuries merely by looking at Kilpatrick's shoulder before and after the use of Breg's pain pump. The district court did not abuse its discretion in finding Dr. Poehling's methodology to establish specific causation unreliable under Daubert.

V. Conclusion

The district court conducted an exhaustive and thorough review of the evidence Kilpatrick submitted to support causation, and concluded that his expert

witness did not employ a reliable methodology to support his conclusions. This court has carefully reviewed the same evidence and finds that the district court did not abuse its broad judicial discretion in so holding. We are aware that courts in other circuits have taken a more expansive approach and permitted expert testimony in similar situations. See McClellan v. I-Flow Corp., ___ F. Supp. 2d ___, 2010 WL 1753261 (D. Or. Apr. 29, 2010); Schott v. I-Flow Corp., ___ F. Supp. 2d ___, 2010 WL 1008478 (S.D. Ohio Mar. 16, 2010). However, Kilpatrick's briefs suffer from a paucity of binding precedent to support his position, and with good reason. The law of this Circuit is clear that the district courts are given broad discretion with wide latitude in conducting a Daubert analysis and concluding that methodologies based on speculative literature and temporal proximity analysis such as the type relied upon by Dr. Poehling are not sufficient to pass Daubert review.

We have previously held that "the abuse of discretion standard allows 'a range of choice for the district court, so long as that choice does not constitute a clear error of judgment." Rasbury v. Internal Revenue Service (In re Rasbury), 24 F.3d 159, 168 (11th Cir. 1994) (quoting United States v. Kelly, 888 F.2d 732, 745 (11th Cir. 1989)). The size of that range – particularly when dealing with evidentiary issues – is significant, and we defer to a district court's evidentiary

rulings to a considerable extent. Brown, 415 F.3d at 1265. In particular, the abuse of discretion standard "thrives" when addressing Daubert issues. Id. at 1265-66. See Kumho tire, 526 U.S. at 152-53; United States v. Abreu, 406 F.3d 1304, 1305-07 (11th Cir. 2005); McClain, 401 F.3d at 1238. Given the facts of this case, the law of this Circuit, and particularly in light of the deferential standard of review afforded district courts in these cases: "the heavy thumb – really a thumb and a finger or two – that is put on the district court's side of the scale," the court concludes that it was not an abuse of discretion to exclude the expert opinion of Dr. Poehling in this case. Brown, 415 F.3d at 1268.

AFFIRMED