UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA

Case No. 08-10052-CIV-MOORE/SIMONTON

DOUGLAS C. KILPATRICK,

Plaintiff,

vs.

BREG, INC.,

Defendant.

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ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT; GRANTING DEFENDANT'S MOTION TO EXCLUDE CAUSATION TESTIMONY

THIS CAUSE came before the Court upon Breg's Motion for Summary Judgment (dkt # 69) and Breg's Motion to Exclude Causation Testimony (dkt # 71).

UPON CONSIDERATION of the Motions, the responses, the pertinent portions of the record, and being otherwise fully advised in the premises, the Court enters the following Order.

I. BACKGROUND

Plaintiff Douglas Kilpatrick ("Kilpatrick") is the owner and operator of a charter fishing guide service in the Florida Keys. In 2004, Kilpatrick visited orthopedic surgeon Dr. John Papilion ("Papilion"), complaining of pain in his right shoulder. Papilion performed an X-ray and an MRI scan which identified a tear in Kilpatrick's labrum, the ring of tissue that surrounds the shoulder socket, or glenoid. To correct the problem, Papilion performed arthroscopic shoulder surgery on Kilpatrick on October 5, 2004.

In order to control post-operative pain, Papilion, during the surgery, inserted into Kilpatrick's shoulder joint a pain pump manufactured by Defendant, Breg, Inc. ("Breg").

Kilpatrick alleges that per Breg's product instructions, Papilion then injected 20 cc's of the anesthetic .5% bupivacaine[1] via the pain pump's attached catheter into Kilpatrick's shoulder, and further filled the pump with 100 cc's of bupivacaine, which the pump was to deliver into Kilpatrick's shoulder over the next forty-eight hours. Kilpatrick successfully completed post-operative physical therapy and was able to return to work for the 2005 fishing season. Kilpatrick claims that while working during that season, he noticed some popping in his shoulder, but at the end of the season felt better.

However, during the 2006 season, Kilpatrick claims he began to experience severe shoulder pain and limited motion while working. Kilpatrick returned to Papilion, who, after additional testing, diagnosed Kilpatrick in October of 2006 with glenohumeral chondrolysis—a breakdown of the cartilage in Kilpatrick's shoulder joint. On November 13, 2006, orthopedic surgeon Dr. John Uribe ("Uribe") performed a total shoulder replacement on Kilpatrick. Kilpatrick states that he will have to undergo several more such procedures during his lifetime.

On July 28, 2008, Kilpatrick filed the instant Complaint (dkt # 1). Kilpatrick alleges that, as a direct result of being administered bupivacaine via Breg's pain pump, he now suffers from permanent and incurable injuries, including debilitating shoulder pain, that have severely and negatively impacted his ability to work, resulting in economic harm in the form of past and future medical expenses. The Complaint asserts five strict product liability claims against Breg for design defect (Count I), defect due to inadequate warning (Count II), defect due to nonconformance with representations (Count III), and defect due to failure to adequately test (Count IV). The Complaint also includes a claim for negligence (Count V), and for violation of

[1] A trade name for bupivacaine is "marcaine," and the Parties' filings use both names. Kilpatrick's causation expert has testified that both names refer to the same chemical. See Deposition of Dr. Gary Poehling, at pp. 63:8-9 (dkt # 72-2) (hereinafter "Poehling Dep."). For convenience, this Order will use the term "bupivacaine." It is undisputed that Breg manufactured only the pain pump used in Kilpatrick's surgery, not the bupivacaine.

the Florida Deceptive and Unfair Trade Practices Act, §§ 501.201-213, Florida Statutes (Count VI).

Breg has filed a motion pursuant to Federal Rule of Evidence 702 to exclude Kilpatrick's evidence of the causation of his injury (dkt # 71). Breg has also moved for summary judgment (dkt # 69) on the grounds that Kilpatrick has not sufficiently demonstrated that Breg's pain pump could and did cause the type of injury Kilpatrick suffered.

II. DISCUSSION

Because the resolution of Breg's summary judgment motion turns on whether Kilpatrick has provided enough admissible evidence to show an issue of material fact as to whether Breg's pain pump caused Kilpatrick's injury, the Court finds it appropriate to first resolve Breg's Rule 702 motion.[2]

A. Breg's Motion to Exclude Causation Testimony

1. Standard of Review

Federal Rule of Evidence 702 sets out the following requirements for expert testimony:

> 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.

Fed. R. Evid. 702. The U.S. Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), and its progeny, govern the application of Rule 702.

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[2] As a threshold matter, the Court notes that it has jurisdiction over this matter pursuant to 28 USC § 1332 because the Parties are diverse and the amount in controversy exceeds $75,000. The Parties stipulate that Florida substantive law on strict products liability and negligence applies. See Amended Pretrial Stipulation at p.4 (dkt # 155).

Under Rule 702 and Daubert, district courts must act as "gatekeepers," admitting expert testimony only if it is both reliable and relevant, to prevent speculative and unreliable testimony from reaching the jury. Rink v. Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005). Specifically, the district court must consider whether 1) the expert is qualified to testify competently regarding the matters he intends to address; 2) the methodology by which the expert reaches his conclusions 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. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562-63 (11th Cir. 1998) (footnote omitted). In the Eleventh Circuit, these three considerations are known as "qualifications, reliability, and helpfulness," and must not be conflated by the district court. U.S. v. Frazier, 387 F.3d at 1246, 1260 (11th Cir. 2004). The party offering the expert bears the burden of satisfying each of the three elements by a preponderance of the evidence. Rink, 400 F.3d at 1292 (citations omitted).

The district court enjoys "broad latitude" in deciding whether expert testimony is reliable, and in how to conduct that inquiry. See Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1312 (11th Cir. 2000) (citing Kumho Tire Co. v. Carmichael, 526 U.S. 137, 142 (1999)). "This deferential standard is not relaxed even though a ruling on the admissibility of expert evidence may be outcome-determinative." Allison v. McGhan Medical Corp., 184 F.3d 1300, 1306 (11th Cir. 1999) (citing General Electric Co. v. Joiner, 522 U.S. 136, 142-43 (1997)).

With the foregoing in mind, the Court has reviewed the voluminous record in this case, including the expert report of Dr. Gary Poehling, M.D. ("Poehling"), Poehling's deposition

testimony, and the medical literature upon which he based his opinions, and has concluded that his testimony on the causation of chondrolysis must be excluded pursuant to Rule 702.[3]

2. Qualifications

Poehling easily meets the qualification prong of Rule 702. The qualification standard for expert testimony is "not stringent," and "so long as the expert is minimally qualified, objections to the level of the expert's expertise [go] to credibility and weight, not admissibility." Hendrix v. Evenflo Co., Inc., 255 F.R.D. 568, 585 (N.D. Fla. 2009) (citations and quotation marks omitted). Breg does not challenge Poehling's qualifications to opine on the cause of chondrolysis, conceding that Poehling has had a long and accomplished career in the field of orthopedics, has been an editor on one of the nation's leading peer-reviewed orthopedics journals for twenty years—serving as editor-in-chief since 1992—has been a practicing orthopedic surgeon and professor of orthopedics, and has authored numerous lectures, speeches, articles, and other writings on topics related to orthopedics. See Poehling Curriculum Vitae (dkt # 104-7). The Court finds that Poehling is more than minimally qualified to offer an opinion on the cause of Kilpatrick's injury.

3. Reliability

The reliability prong of Rule 702 is at the heart of the Parties' dispute. The reliability inquiry requires the court to independently analyze each step in the logic leading to the expert's conclusions; if the court determines that any step in the expert's chain of logic is unreliable, his entire opinion must be excluded. McClain v. Metabolife Int'l Inc., 401 F.2d 1233, 1245 (11th Cir. 2005). In determining reliability, the Court may consider the following non-exclusive factors: "(1) whether the expert's theory can be and has been tested; (2) whether the theory has

[3] Because Poehling's testimony must be excluded for failure to satisfy Rule 702's reliability prong, the Court does not reach the helpfulness prong.

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." See McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1256 (11th Cir. 2002) (citing Daubert, 509 U.S. at 593-94).

However, these factors are not the "definitive checklist or test" for reliability, see Daubert, 509 U.S. at 593, and in some cases, evidence which does not meet all or even most of these factors may still be admissible, because other factors may predominate. U.S. v. Brown, 415 F.3d 1257, 1267-68 (11th Cir. 2005). Although the pertinent criteria for reliability may vary case by case, to be reliable the expert's testimony must always be based on "good grounds," see Daubert, 509 U.S. at 590; "leaps of faith" unsupported by good science preclude the admission of the expert's testimony. Rider v. Sandoz Pharmaceuticals, 295 F.3d 1194, 1202 (11th Cir. 2002). The objective of the gatekeeping inquiry "is to 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 Tire Co., 526 U.S. at 152.

Breg argues, and Kilpatrick does not contest, that this case should be treated like a toxic tort case for purposes of the Daubert inquiry, requiring Kilpatrick to offer proof of both general causation—whether the agent in question can cause harm of the type Kilpatrick alleges—and proof of specific causation—whether the agent in fact did cause Kilpatrick's injury. See McClain, 401 F.3d at 1239. If anything, determining causation in this case requires an even more complex logical chain than the typical toxic tort case, because the key issue is not merely whether a chemical compound could and did cause injury, but whether that compound as delivered via a particular medical device inserted in a particular location (within Kilpatrick's

shoulder joint) could and did cause injury. Poehling has acknowledged this distinction, stating that he does not believe it is Breg's pain pump *per se* that causes chondrolysis, but the bupivacaine delivered via the pain pump that causes it. See Poehling Dep., at pp. 99:2-6 (dkt # 72-2) ("I don't think an intra-articular catheter causes glenohumeral chondrolysis. I think it is the bupivacaine that goes through that catheter that causes the glenohumeral chondrolysis."). Further, the Parties do not dispute that glenohumeral chondrolysis is a medical phenomenon that has emerged only recently, and that the first study suggesting its linkage with intra-articular pain catheters appeared only in 2006. Even Kilpatrick concedes that the medical literature supporting his claim is still a "developing science." See Pl.'s Resp. to Def. Mot. for Summ. J., at p.6 (dkt # 102). It is almost *de rigeur* in Daubert opinions to quote Judge Posner's observation that "[l]aw lags science; it does not lead it," Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996), but in light of the foregoing, it is particularly true in this case. Accordingly, the general causation inquiry takes on special importance here.

a. Literature Poehling Relies on Is Insufficient to Show Causation

In reaching his conclusions on general causation in this case, Poehling did not personally conduct any independent research; rather, he relied upon several medical journal articles. See Poehling Dep. at pp. 37:6-38:8 (dkt # 72-2). Poehling acknowledges that none of those articles were based on controlled, randomized epidemiological studies of human beings, which traditionally are considered the best form of statistical evidence for proving causation.[4] Kilpatrick argues, plausibly, that randomized human epidemiological studies would not be ethical or feasible under the circumstances and that such studies are not necessary to carry his burden on a Daubert motion. It is true enough that a lack of epidemiological evidence is not fatal

[4] "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.

to Kilpatrick's case. See Rider, 295 F.3d at 1199. But this only heightens the need for Poehling to present other forms of highly persuasive scientific evidence to lay a foundation for his expert opinions. He has failed to do so.

Kilpatrick proffers an extensive list of articles that Poehling purportedly relied upon in preparing his expert report. However, when questioned during his deposition as to which articles support his conclusion that bupivacaine delivered via an intra-articular pain pump catheter can cause chondrolysis, Poehling pointed only to four[5]: a study of 152 patients who had undergone arthroscopic shoulder surgery (the "Hansen study"),[6] a study of rabbits whose shoulders were injected with bupivacaine (the "Gomoll study"),[7] a case report of two teenage female arthroscopic surgery patients who developed chondrolysis (the "Greis report"),[8] and a one-page editorial that Poehling had co-authored.[9] Only the first of these articles was a comparative study of humans who had undergone arthroscopic surgery involving pain pumps. Significantly, none of the articles explains the mechanism by which bupivacaine damages cartilage,[10] each has important limitations that Poehling does not take into account,[11] and none of them offers an ultimate conclusion as to the general causation of glenohumeral chondrolysis. At best, some of

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[5] See Poehling Dep., at pp.43:20-45:10; 143:8-147:17 (dkt # 72-2).
[6] Brent P. Hansen et al., Postarthroscopic Glenohumeral Chondrolysis, 35 Am. J. Sports Med., July 2007, 1628-34 (dkt # 72-3).
[7] Andreas Gomoll et al., Chondrolysis After Continuous Intra-Articular Bupivacaine Infusion: An Experimental Model Investigating Chondrotoxicity in the Rabbit Shoulder, 22 Arthroscopy, Aug. 2006, 813-19. (dkt # 105-2).
[8] Patrick Greis et al., Bilateral Shoulder Chondrolysis Following Arthroscopy: A Report of Two Cases, 90 J. Bone & Joint Surgery, June 2008, 1338-44 (dkt # 105-7).
[9] James Lubowitz & Gary Poehling, Editorial, 25 Arthroscopy, July 2007, 223, 223 (dkt # 105-8).
[10] See In re Accutane Prods. Liability Litig., 511 F. Supp. 2d 1288, 1295 (M.D. Fla. 2007) (excluding expert testimony where "no one knows the biological mechanism by which [the condition in question] occurs").
[11] See id. at 1291 ("When an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study. That is, he must not draw overreaching conclusions.") (citing McClain, 401 F.3d at 1245-47).

them tend to show an association between chondrolysis and intra-articular pain pump use, but as the Eleventh Circuit has recognized, "showing *association* is far removed from proving *causation*." Allison,184 F.3d at 1315 n.16 (emphasis in original); see also In re Accutane Prods. Liability Litig., 511 F. Supp. 2d 1288, 1297 (M.D. Fla. 2007) ("[A]n association is not equivalent to causation . . .") (citations omitted). The Court will now review each of these articles in turn.

Poehling characterizes the Hansen study (dkt # 72-3) as the "strongest" evidence for a connection between intra-articular pain pumps and chondrolysis. See Poehling Dep., at p. 145:13-17 (dkt # 72-2). The Hansen study examined 152 patients who underwent 177 shoulder surgeries. Only nineteen shoulders in seventeen patients had bupivacaine-dispensing pain pumps inserted into them. Of those, twelve shoulders in ten patients developed chondrolysis. Kilpatrick, and Poehling, claim that this 63% injury rate (i.e. twelve chondrolytic shoulders out of nineteen treated with pain pumps) is powerful evidence of general causation. However, the Hansen study includes no statistical analysis, and therefore no means of determining whether the findings are statistically significant, or whether it is statistically meaningful to extrapolate from the relatively small sample size. Further, the study noted that thermal energy, another suspected cause of chondrolysis, was used in four cases, but did not explain whether thermal energy contributed to or wholly accounted for the chondrolysis in those cases, beyond a vague statement that "it [thermal energy] does not appear to be clearly proven to be the only factor in these cases." See Hansen study (dkt # 72-3, at 14). The study purported to identify a "strong association" between chondrolysis and intra-articular pain pumps, but also acknowledged that "[t]hermal and/or radiofrequency, suture material, and reabsorbable suture anchors may have played a role not yet completely understood at this time." Id. at 15. Unlike Poehling, the Hansen

study declined to reach a conclusion as to the general causation of chondrolysis. Even assuming that arthroscopic shoulder surgery patients treated with intra-articular pain pumps suffer chondrolysis at the same rate observed in the Hansen study, nothing explains why nearly 40% of patients treated with pain pumps did not develop chondrolysis. In his deposition, Poehling acknowledged that he has no explanation:

> A. . . . You know, there is some reason that 40 percent of people that got in Hansen's study somehow survived—their articular cartilage survived, so is there something in those patients that are protective . . . you have to say that there is a difference, because 40 percent didn't have it, so what is it that protected them. Is it something in the synovial fluid that is different, is there—is there some sort of protein that they have. You know, I don't know.

Poehling Dep., at pp.138:23-139:10 (dkt # 72-2); see also id. at 103:14:-25. Extrapolating from the Hansen study that intra-articular pain pumps cause chondrolysis, then, effectively leaves an unexplained 40% error rate in Poehling's hypothesis. This is not the "good science" that Daubert and Rule 702 demand.

The second article on which Poehling based his conclusions, the Gomoll study, is a controlled study of rabbits (dkt # 105-2). The authors reported statistically significant evidence of chondrolysis among an experimental group of rabbits whose shoulders were infused with bupivacaine over a 48-hour period, as contrasted with a control group of rabbits injected with saline solution. However, the authors were careful to limit their conclusions, noting that further study was warranted "because epidemiologic study of chondrolysis in humans will require an extremely large sample size because of the low incidence and prevalence of this condition . . ." Id. at 6. The authors noted that "although we were able to show the detrimental effects of bupivacaine on the cellular and tissue level in a rabbit model, it remains to be determined whether human cartilage is equally susceptible and whether these . . . changes result in the subsequent development of rapidly progressive osteoarthritis." Id. at 5. The courts have also

recognized the difficulty inherent in extrapolating conclusions about human disease from animal-based studies. See, e.g., Accutane, 511 F. Supp. 2d at 1291-1292 (discussing advantages and disadvantages of animal studies). One "significant disadvantage" of animal studies is that "differences in absorption, metabolism and other facts may result in interspecies variation in responses"; another disadvantage is that "the high doses customarily used in animal studies require consideration of the dose-response relationship and whether a threshold no-effect dose exists." See id. (quoting Michael D. Green et al., Reference Guide on Epidemiology, in Reference Manual on Scientific Evidence, 333, 345-46 (Federal Judicial Center, 2d. ed. 2000)). This second consideration, the dose-response relationship, is particularly important here, because the authors of the Gomoll study acknowledge that "no data exist regarding the human-equivalent dosing of intra-articular bupivacaine in a rabbit shoulder model . . ." See Gomoll study (dkt # 105-2 at 2). This admission undercuts the Gomoll study's applicability to human chondrolysis.

The difference in the dose-response relationship between animals and humans is not trivial: dose-response relationship is, in fact, "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 expert who avoids or neglects this principle of toxic torts without justification casts suspicion on the reliability of his methodology." Id. In reaching his conclusions on human chondrolysis causation, Poehling did not account for or explain the possible differences in dose-response relationship between humans and rabbits, rendering his methodology questionable. See Accutane, 511 F. Supp. 2d at 1292-93

[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 1241-42 (citations omitted).

(excluding expert testimony based in part on dog study where expert did not consider differences in dose-response relationship between dogs and humans).

The third article upon which Poehling based his conclusion, the Greis report, was a report of two cases of female swimmers, one aged fourteen and the other eighteen, who developed chondrolysis after undergoing arthroscopic shoulder surgery involving bupivacaine-dispensing, intra-articular pain pumps (dkt # 105-7). Once again, the authors of the study were more cautious than Poehling in reaching an ultimate conclusion as to causation, acknowledging that "we realize that the exact cause of the chondrolysis remains unknown." See id. at 6. Furthermore, anecdotal reports of two individuals are, of course, not statistically significant evidence of causation. As Poehling acknowledges, case reports are "way down at the very bottom as far as medical strength of an article" and cannot establish medical causation. Poehling Dep., at p.90:8-23 (dkt # 72-2). The Eleventh Circuit has likewise recognized that case reports on their own are not especially useful as proof of causation. See McClain, 401 F.3d at 1254 ("Simply stated, case reports raise questions; they do not answer them"); Rider, 295 F.3d at 1199 ("[W]hile they may support other proof of causation, case reports alone ordinarily cannot prove causation"). Accordingly, Poehling's extrapolation of a general cause for chondrolysis from this anecdotal case report is unwarranted and unreliable.

The final piece of literature Poehling claims to have relied upon is a 228-word editorial that Poehling himself co-authored (dkt # 105-8). The editorial is not a case report or study of any kind, and does not offer an opinion on the causation of chondrolysis, but rather states that "[t]he etiology of glenohumeral chondrolysis may be multifactorial. Further research is required to determine the cause, and proper prevention, of shoulder chondrolysis." See id. The editorial also notes that "idiopathic" chondrolysis—that is, chondrolysis caused by unknown factors—has

also been described in the medical literature. See id. By Kilpatrick's own admission, the Poehling editorial "is general in nature and does not present any factual context that would allow the court to discern its relevance to this case." See Pl.'s Statement of Material Facts in Opp. to Def.'s Mot. for Summ. J., at ¶ 3 (dkt # 103). The Poehling editorial is, to say the least, inadequate as a basis for a scientific judgment about the general causation of chondrolysis.

b. Poehling Does Not Explain Background Risk

Even if the studies Poehling claims to have relied upon did support his conclusions about the causation of chondrolysis, there are additional problems with his methodology. Specifically, Poehling has not offered a sufficient explanation of the background risk for glenohumeral chondrolysis. Background risk "is not the risk posed by the chemical or drug at issue in the case. It is the 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 1243 (emphasis in original). "A reliable methodology should take into account the background risk." Id.

Kilpatrick claims that the background risk of chondrolysis is "for all intent[s] and purposes zero." See Pl.'s Mem. in Opp. to Def.'s Mot. for Summ. J., at p.1 (dkt # 102). But this is demonstrably incorrect. Poehling acknowledged in his editorial, and in his deposition, that chondrolysis can arise idiopathically—that is, from unknown causes. See Poehling Dep., at p.70:10-20 (dkt # 72-2). If chondrolysis can occur without any known cause, it cannot be that the background risk for it is "zero." Whatever the true background risk, Poehling has not endeavored to explain it, and this casts further doubt on the reliability of his methodology.

c. Poehling Concedes That the Literature Has Not Reached a Conclusion as to the Cause of Chondrolysis

Although Kilpatrick offers Poehling's testimony for the purposes of proving general causation, Poehling, when asked in his deposition whether intra-articular pain pumps are still only a "hypothetical or speculative" cause of glenohumeral chondrolysis, repeatedly answered in the affirmative. Several exchanges from the transcript of his deposition are worth highlighting:

> Q: Do you agree, Dr. Poehling, that based on the available body of medical and scientific literature even today as of May 15, 2009, it is still only hypothetical or speculation that the intra-articular application of a catheter from a continuous flow pain pump medically causes glenhumeral chondrolysis, correct?
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> A: *Well, that's a—correct statement and I can't argue with that.* But those are words and it makes it sound like we don't know what we're doing and that, gosh, guys, it might be all right for you to go and put this in because we're really not sure, and I—that isn't the case . . .
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> ***
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> Q: I understand that's your personal opinion, Dr. Poehling, but I'm asking you, on the general causation aspect, based on the available body of medical literature and science, this body of evidence that you talked about earlier in your response, would you agree with me, Dr. Poehling, that there is nothing in the available medical and scientific literature today as of May 15, 2009, which establishes causation between the intra-articular placement of a catheter that is part of a continuous flow pain pump and the condition of glenohumeral chondrolysis?
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> A: Again, *you're specifically right* and I don't think I need to say what I feel otherwise.

Poehling Dep., at pp. 97:6-17; 99:7-19 (dkt # 72-2) (emphasis added). Poehling's concession that the current state of the medical literature is still unsettled about the cause of chondrolysis seriously undermines the reliability of his methodology. As Breg correctly notes, the Court cannot make up for the scientific leaps required to reach a conclusion on causation simply by viewing all of Kilpatrick's evidence as a whole:

> Conclusions 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 that 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 proferred.

General Electric Co., 522 U.S. at 146, overruling Joiner v. General Electric Co., 78 F.3d 524 (11th Cir. 1996) (suggesting that evidence should be viewed "in its entirety" for Daubert purposes).

This Court has reviewed the studies Poehling claims to rely upon, and found that Poehling's extrapolations from them regarding causation are not warranted. What is more, Poehling, when pressed, essentially admits the same thing. Poehling's methodology has no known rate of error—to the extent one can be extrapolated from the Hansen study, it is an unexplained 40%—and at most, all he can offer is a hypothesis that "may be exactly right," but that right now is "merely plausible, not proven." Accutane, 511 F. Supp. 2d at 1296. "[B]iological possibility is not proof of causation." Id. Under the circumstances, the Court would be derelict in the gatekeeping duties imposed on it by Daubert and Rule 702 if it found Poehling's testimony on general causation reliable.

d. Poehling's Conclusions on Specific Causation are Also Unreliable

To carry his burden on causation, Kilpatrick must show sufficient evidence of specific causation as well as general causation. See McClain, 401 F.3d at 1239. Kilpatrick's failure to present reliable evidence of general causation alone requires that Breg's Daubert motion be granted. However, Poehling's testimony about specific causation is also unreliable, because it is ultimately premised upon temporal relationship and the *post hoc ergo propter hoc* fallacy. "The *post hoc ergo propter hoc* fallacy 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. at 1243.

In describing how he concluded that Kilpatrick's chondrolysis was caused by the use of Breg's pain pump, Poehling described a process of differential diagnosis, ruling out other suspected causes of chondrolysis such as thermal energy and "gentian violet."[13] Poehling Dep., at pp. 85:21-87:21 (dkt # 72-2). Differential diagnosis means, in layman's terms, determining the cause of a disease by process of elimination.[14] Differential diagnosis "may offer an important component of a valid methodology" in determining specific causation, but it "will not usually overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug . . ." McClain, 401 F.3d at 1252-53. Ultimately then, because Poehling's testimony fails on the general causation prong, differential diagnosis does not suffice to carry Kilpatrick's burden on the specific causation prong.

However, even if Poehling's testimony satisfied the general causation inquiry, his conclusion on specific causation would still be unreliable for a more fundamental reason: it is ultimately rooted in nothing more than temporal relationship. It may be "almost irresistible to conclude that what happens shortly after the event must have been caused by the event," but that is not the basis of good science. Accutane, 511 F. Supp. 2d at 1300. Yet this is precisely what Poehling does in describing his diagnosis of Kilpatrick's 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 bupivacaine is what caused it, and I don't think that that's just me or—I think any real scientist.

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[13] The Parties describe gentian violet as a "contrast dye" that is sometimes injected into a patient's shoulder during arthroscopic surgery, but do not explain its purpose or function.

[14] See McClain, 401 F.3d at 1252 ("Differential diagnosis involves 'the determination of which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their clinical findings.'") (citations omitted). "The more precise but rarely used term is differential etiology . . . [t]he etiology of a disease is the cause or origin of the disease . . ." Id.

Poehling Dep., at p. 96:13-19 (dkt # 72-2) (emphasis added). Determining causation based on "what the patient looked like before" versus "what he looks like now" is the very definition of the *post hoc ergo propter hoc* fallacy. It is not a valid basis for scientific conclusions about specific causation, and Poehling's dependence upon it further weakens the reliability of his methodology.

e. Kilpatrick Has Not Shown Any Other Valid Basis for Determining Causation

As noted above, Kilpatrick points to various other articles that he claims provide evidence of the causation of chondrolysis, but when questioned during his deposition about medical literature that supports his conclusions, Poehling cited only the studies discussed above. See Poehling Dep., at pp.43:20-45:10; 143:8-147:17 (dkt # 72-2). Breg correctly argues that where an expert witness is "unable to explain why these studies help inform her conclusion . . . plaintiff's counsel cannot fill in the gaps." In re Human Tissue Prods. Liability Litig., 582 F. Supp. 2d 664, 667 (D.N.J. 2008). A review of the literature that Poehling based his opinion on reveals that those articles do not support his conclusions without "leaps of faith" prohibited by Rule 702.

Kilpatrick points to some of Breg's internal documents to bolster his arguments on causation. However, neither Kilpatrick nor Poehling suggest that Poehling relied on these documents in reaching his conclusions, and they are therefore irrelevant to the Daubert inquiry. At most, Breg's documents, like the articles that Poehling relied upon, mention an association between pain pumps an chondrolysis, which, as discussed, is not equivalent to causation. See Accutane, 511 F. Supp. 2d 1288 (excluding expert testimony where expert claimed to have relied on defendant's internal documents in reaching conclusions on causation; if defendant's

documents had admitted causation, "this Court could have saved a lot of time—this opinion would have been unnecessary.").

B. Breg's Motion for Summary Judgment

1. Standard of Review

The applicable standard for reviewing a summary judgment motion is unambiguously stated in Rule 56(c) of the Federal Rules of Civil Procedure:

> The judgment sought should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

Summary judgment may be entered only where there is no genuine issue of material fact. Twiss v. Kury, 25 F.3d 1551, 1554 (11th Cir. 1994). The moving party has the burden of meeting this exacting standard. Adickes v. S.H. Kress & Co., 398 U.S. 144, 157 (1970). An issue of fact is "material" if it is a legal element of the claim under the applicable substantive law which might affect the outcome of the case. Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997). An issue of fact is "genuine" if the record taken as a whole could lead a rational trier of fact to find for the nonmoving party. Id.

In applying this standard, the district court must view the evidence and all factual inferences therefrom in the light most favorable to the party opposing the motion. Id. However, the nonmoving party "may not rely merely on allegations or denials in its own pleading; rather, its response must—by affidavits or as otherwise provided in this rule—set out specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(e)(2). "The mere existence of a scintilla of evidence in support of the [nonmovant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmovant]." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986)

2. Causation

Causation is an element common to all of Kilpatrick's claims. To sufficiently establish causation for a negligence claim in a products liability action, the plaintiff bears the burden of proving by a preponderance of the evidence that his injury was proximately caused by the manufacturer's breach of its duty to produce a product reasonably safe for use. See Indem. Ins. Co. of N. Am. v. Am. Aviation, Inc., 344 F.3d 1136, 1146 (11th Cir. 2003) (applying Florida law). To prove causation under a strict products liability theory, the plaintiff bears the burden of proving that the product defect proximately caused his injury. See McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1257 (11th Cir. 2002) (citing Edward M. Chadbourne, Inc. v. Vaughn, 491 So. 2d 551, 553 (Fla. 1986)). Causation is also one of the elements of a claim arising under the Florida Deceptive and Unfair Trade Practices Act. See City First Mortg. Corp. v. Barton, 988 So. 2d 82, 86 (Fla. 4th Dist. Ct. App. 2008) (elements of FDUTPA claim are deceptive act or unfair practice, causation, and actual damages) (citations omitted).

Kilpatrick's failure to proffer sufficient evidence of causation, an element critical to all of his claims, is necessarily fatal to his efforts to avoid summary judgment. See Rink, 400 F.3d at 1294-96 (affirming grant of summary judgment where plaintiff's expert evidence was unreliable to prove causation); Allison, 184 F.3d at 1320 (same). Poehling is Kilpatrick's sole designated expert on the issue of causation. Kilpatrick's only other possible source of evidence on causation is the testimony of Kilpatrick's two treating physicians, Papilion and Uribe. Treating physicians not offered as experts, however, may only testify as lay witnesses to matters within the scope of their own personal observation, such as treatment. See U.S. v. Henderson, 409 F.3d 1293, 1300 (11th Cir. 2005) (treating physician impermissibly offered expert testimony on causation, where determining causation was not necessary to either diagnosis or treatment). Because Uribe and

Papilion have neither been designated as experts nor completed expert reports pursuant to Federal Rule of Civil Procedure 26, their testimony would necessarily be limited to matters of personal observation and cannot touch upon causation. See, e.g., Widhelm v. Wal-Mart Stores, Inc., 162 F.R.D. 591, 594 (D. Neb. 1995) (treating physicians not required to complete expert report to offer expert testimony on treatment, but plaintiffs' attempts "to solicit expert testimony about causation . . . will not be permitted"). In the absence of any reliable expert evidence on causation, summary judgment must be granted in favor of Breg.

III. CONCLUSION

Based on the foregoing, it is

ORDERED AND ADJUDGED that Breg's Motion to Exclude Causation Testimony (dkt # 71) is GRANTED. It is further

ORDERED AND ADJUDGED that Breg's Motion for Summary Judgment (dkt # 69) is GRANTED. The Clerk of Court is directed to CLOSE this case. All pending motions not otherwise ruled upon are DENIED AS MOOT.

DONE AND ORDERED in Chambers at Miami, Florida, this 25th day of June, 2009.

K. MICHAEL MOORE
UNITED STATES DISTRICT JUDGE

cc: All counsel of record