

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

KAID C. MUSGRAVE, et al.,

Plaintiffs,

v.

**BREG, INC. AND LMA,
NORTH AMERICA, Inc., et al.,**

Defendants.

Case No. 2:09-cv-01029

JUDGE GREGORY L. FROST

Magistrate Judge Mark R. Abel

OPINION AND ORDER

This matter is before the Court on Plaintiffs' ten motions *in limine* (ECF No. 158) and Breg's memorandum in opposition to Plaintiffs' motions *in limine* (ECF No. 160). For the reasons that follow, the Court **DENIES AS MOOT IN PART AND DENIES IN PART** Plaintiffs' ten motions *in limine*.

I. Background

Plaintiff Kaid C. Musgrave was seventeen years old in 2003 when he injured his right shoulder during a high school football game. On November 4, 2003, Dr. Brad E. Brautigan performed arthroscopic surgery on Musgrave's shoulder at the Zanesville Surgery Center in Zanesville, Ohio. After the surgery, Dr. Brautigan prescribed and implanted the catheter of a Breg infusion pain pump to administer local anesthetic for post-operative pain control. Dr. Brautigan used a Breg PainCare 3200 and placed the catheter intra-articularly, *i.e.*, inside the shoulder joint. Dr. Brautigan prescribed 0.5% Marcaine (an anesthetic known generically as bupivacaine) for use in the pump. The pain pump was removed two days later, on November 6, 2003.

Musgrave continued to experience problems with his right shoulder, and on December 17, 2004, underwent a second arthroscopic surgery. During this surgery, Dr. Brautigam observed osteoarthritic changes to the glenohumeral joint. Less than two years after using the Breg pain pump, Musgrave developed chondrolysis, which is the rapid loss of joint cartilage following some chemical, mechanical, infectious, immunological, or thermal insult. *See* Daniel J. Soloman, *et al.*, Glenohumeral Chondrolysis After Arthroscopy: A Systematic Review of Potential Contributors and Causal Pathways, *Arthroscopy* 25:11:1329 (2009). The result of this cartilage loss is a joint that no longer has a smooth gliding surface to cover the ends of the bone, so the joint rubs bone against bone causing pain and stiffness. Due to this condition, Musgrave underwent a total right shoulder arthroplasty. He has a complete loss of cartilage in his shoulder and degenerative bone loss.

Musgrave and his parents (together “Plaintiffs”) filed this action on November 13, 2009. Plaintiffs claim that the post-operative continuous injection of anesthetics directly into Musgrave’s shoulder joint caused chondrolysis, leaving him with serious and permanent cartilage damage. Plaintiffs’ complaint contains claims for relief against Breg for products liability, based on Breg’s alleged inadequate warning regarding intra-articular injection of anesthetics and/or use of the pain pump after orthopedic surgery, the Breg PainCare 3200 pain pump’s alleged defective design, and Breg’s alleged breaches of express and implied warranties. Plaintiffs also alleged claims for common law fraud and punitive damages.

On September 2, 2011, this Court granted Breg’s Motion for Summary Judgment as it related to Plaintiffs’ common law breach of implied and/or express warranty claims and denied the remainder of Breg’s motion.

II. Standard

Although neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize the Court to rule on an evidentiary motion *in limine*, the United States Supreme Court has noted that the practice of ruling on such motions “has developed pursuant to the district court’s inherent authority to manage the course of trials.” *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). The purpose of a motion *in limine* is to allow the Court to rule on issues pertaining to evidence in advance of trial in order to avoid delay and ensure an even-handed and expeditious trial. See *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004) (citing *Jonasson v. Lutheran Child & Family Servs.*, 115 F.3d 436, 440 (7th Cir. 1997)).

Courts, however, are generally reluctant to grant broad exclusions of evidence *in limine*, because “a court is almost always better situated during the actual trial to assess the value and utility of evidence.” *Koch v. Koch Indus., Inc.*, 2 F. Supp.2d 1385, 1388 (D. Kan 1998); accord *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). To obtain the exclusion of evidence under such a motion, a party must prove that the evidence is clearly inadmissible on all potential grounds. See *Ind. Ins. Co.*, 326 F. Supp. 2d at 846; *Koch*, 2 F. Supp. 2d at 1388; *Cf. Luce*, 469 U.S. at 41. “Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context.” *Ind. Ins. Co.*, 326 F. Supp.2d at 846. Denial of a motion *in limine* does not necessarily mean that all evidence contemplated by the motion will be admitted at trial. Denial merely means that without the context of trial, the Court is unable to determine whether the evidence in question should be excluded. *Id.* The Court will entertain objections on individual proffers as they arise at trial, even though the proffer falls within the

scope of a denied motion *in limine*. *Id.* (citing *United States v. Connelly*, 874 F.2d 412, 416 (7th Cir.1989); *Luce*, 469 U.S. at 4).

III. Federal Rules of Evidence

A. Rules 401 and 402

Federal Rule of Evidence 401 provides:

“Relevant evidence” means evidence having 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.

Federal Rule of Evidence 402 provides:

All relevant evidence is admissible, 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.

B. Rule 403

Federal Rule of Evidence 403 provides:

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.

IV. Discussion

Plaintiffs have filed ten motions *in limine*. The Court will address each *in seriatim*.

A. Motion 1

In their first motion, Plaintiffs request:

The Court should prohibit Breg, Breg’s counsel, and Breg’s witnesses from referring to, or in any way communicating to the jury at trial, that the FDA cleared or considered Breg’s pain pumps safe for intra-articular use. As a necessary correlate, this Court should also preclude any evidence that the FDA never voiced any concerns regarding Breg’s pain pumps. Such evidence is expressly contrary to the facts and would mislead the jury to the prejudice of the Plaintiffs. *See Fed. R.*

Evid. 403.

(ECF No. 158-1 at 2-3.) Breg contends that such a ruling would preclude the jury from hearing all of the evidence. This Court agrees.

As Breg correctly points out, Plaintiffs may argue about what it means, but they cannot keep the jury from hearing the fact that the FDA cleared a general indication for use for the Pain Care 3200, and that Breg understood that general clearance to include orthopedic and intra-articular uses. The Court concludes that the probative value of this evidence is not substantially outweighed by the danger of confusion of the issues or misleading the jury.

In the event that the Court made such a conclusion, Plaintiffs ask:

In the alternative, if Breg is permitted to introduce such evidence, Plaintiffs request that the Court permit Plaintiffs to introduce evidence demonstrating that the United States Department of Justice has expressed concern regarding Breg's pain pumps. In 2010, Breg was served with a subpoena in connection with an official investigation by the United States Attorney for the Central District of California regarding potential Federal health care offenses. . . . Accordingly, if Breg seeks to argue or introduce evidence that the government did not voice any concerns regarding its pain pumps, Plaintiffs should be permitted to question Breg's witnesses and introduce evidence regarding the Department of Justice investigation into Breg's off-label marketing.

(ECF No. 158-1 at 7.) This argument is not well taken.

Magistrate Judge Mark R. Abel denied Plaintiffs' motion to compel correspondence between Breg and the United States Attorney for the Central District of California as well as any subpoenas accompanying that correspondence. (ECF No. 102.) In his decision, Magistrate Judge Abel found that "the subpoena itself merely reflects the thought processes of the Assistant United States Attorney investigating the case, and is, therefore, irrelevant to Plaintiffs' claims." *Id.* at 5. He further found the subpoena irrelevant to Plaintiffs' claims of off-label marketing. Reviewing the same issue in *Schumacher v. Breg*, 10-cv-21, slip op. (S.D. Ohio Nov. 12, 2010),

Magistrate Judge Norah McCann-King agreed with Magistrate Judge Abel and denied the plaintiff's motion to compel production of the correspondence with the Justice Department and the subpoena from the United States Attorney's Office to Breg. The Court agrees with both Magistrate Judges that this evidence is not relevant.

Accordingly, the Court **DENIES** Plaintiffs' first motion *in limine*.

B. Motion 2

Plaintiffs ask the Court to prohibit Breg from utilizing the learned intermediary doctrine. In Ohio, the learned intermediary doctrine is codified in the Ohio Products Liability Act and provides that a "drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician" *Wimbush v. Wyeth*, 619 F.3d 632, 637 (6th Cir. 2010) (quoting Ohio Rev. Code. § 2307.76(C)). Plaintiffs argue that "[a]t no time did Breg fulfill its duty to warn physicians." (ECF No. 158-1 at 7.) Plaintiffs' argument is not well taken.

As Breg correctly notes, this Court has already held, in its Opinion and Order on the parties' cross motions for summary judgment, that there are genuine issues of material fact as to the adequacy of the warnings. Because of this holding, the Court cannot decide the applicability of the learned intermediary doctrine as a matter of law on a motion *in limine*. See *Miller v. Alza Corp.*, 759 F. Supp. 2d 929, 935-36 (S.D. Ohio Dec. 17, 2010) (holding that, to defeat a learned intermediary defense, the plaintiff must prove that the warning was inadequate and that an adequate warning would have influenced the prescribing physician); see also *Wimbush v. Wyeth*, 619 F.3d 632, 638-39 (6th Cir. 2010) (cited by Plaintiffs here and holding that summary judgment on learned intermediary grounds was mandated when the plaintiff "failed to point to

any evidence creating a factual dispute as to the adequacy of warning”). Consequently, the Court **DENIES** Plaintiffs’ second motion *in limine*.

C. Motion 3

Plaintiffs contend that, at trial, Breg may argue that a superseding or intervening cause, such as Dr. Brautigan’s placement of the pain pump into the joint of Kaid Musgrave’s shoulder, enables Breg to escape liability. In response, Breg indicates that, to the extent Plaintiffs seek only to preclude Breg from arguing that Dr. Brautigan’s negligence was an intervening or superseding cause of Musgrave’s injury, Breg does not oppose it because Breg does not intend to offer such argument or evidence. Thus, the Court **DENIES AS MOOT** Plaintiffs’ third motion as it relates to Dr. Brautigan’s negligence as an intervening or superseding cause of Musgrave’s injury.

Breg, however, argues that to the extent Plaintiffs’ motion targets evidence of plausible alternative causes of Kaid Musgrave’s shoulder condition, including the shoulder surgery itself, it should be denied. This Court agrees. The evidence before the Court shows that some experts believe that prior surgery is a risk for cartilage damage and that there are other causes for chondrolysis. This type of evidence is relevant to causation of Musgrave’s shoulder condition. Consequently, the Court **DENIES** Plaintiffs’ third motion *in limine* as it relates to plausible alternative causes of Musgrave’s shoulder condition.

D. Motion 4

Plaintiffs request exclusion of certain specific and general causation testimony offered by Breg’s experts. Plaintiffs’ arguments are not well taken for the same reasons the Court found Breg’s arguments related to exclusion of certain specific and general causation testimony from

Plaintiffs' experts not well taken. (ECF No. 151.)

In short, Plaintiffs' arguments go to the weight to be given the evidence not to its admissibility. In this action, Plaintiffs and Breg have retained eminently qualified experts whose testimony is admissible. This Court's gatekeeper role is not intended to supplant the adversary system or the role of the jury; rather, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993). This Court's role is simply 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. *Wellman v. Norfolk and W. Ry. Co.*, 98 F. Supp. 2d 919, 923-24 (S.D. Ohio 2000). Thus, the Court **DENIES** Plaintiffs' fourth motion *in limine*.

E. Motion 5

Plaintiffs expect that Breg will attempt to offer evidence of Kaid Musgrave's prior injuries to discredit his present claims. Plaintiffs ask the Court to prohibit this evidence because it is irrelevant and prejudicial. Breg, however, argues that Musgrave's medical history and any past shoulder injuries bears directly upon whether his use of a Breg pump caused his shoulder condition. Breg contends that a reliable differential diagnosis must consider patient history and past injuries, and that is precisely what Breg and Dr. Petty have done. This Court agrees. Evidence of Musgrave's past shoulder injuries is relevant and probative of the issue of causation, and its probative value is not substantially outweighed by the danger of unfair prejudice to Plaintiffs. Accordingly, the Court **DENIES** Plaintiffs' fifth motion *in limine*.

F. Motion 6

Plaintiffs object to Breg introducing any evidence to compare the number of times pain pumps have been used with the number of patients who have developed chondrolysis because Breg has failed to lay a sufficient foundation for such evidence. Plaintiffs claim that the purpose of this evidence is to attempt to show that chondrolysis is rare. Breg, in response, argues that this Court has acknowledged the relevance and admissibility of evidence of the nonoccurrence of cases of chondrolysis, without the foundation Plaintiffs now demand. (ECF No. 151 at 6) (incorporating by reference Judge Graham's opinion in *Hamilton v. Breg*).

According to Judge Graham's decision in *Hamilton* in which he denied Breg's *Daubert* challenge, the causation testimony of the plaintiffs' experts was sufficiently reliable to be admissible because they considered the nonoccurrence of cases of chondrolysis following discontinuation of intra-articular pain pump use. *Hamilton v. Breg, Inc.*, No. 09-CV-146, 2011 WL 833614, *6 (S.D. Ohio Jan. 24, 2011) ("The evidence of temporal relationship was similarly compelling, not only because pain pump use preceded the onset of chondrolysis, but also because Drs. Beck and Benz (the surgeon whose patients Dr. Matsen investigated) encountered no additional cases of chondrolysis after they stopped using pain pumps in the joint space."). Just as Plaintiffs' expert Dr. Wells evaluates the occurrence or nonoccurrence of cases of chondrolysis, so too may Breg and its experts. Accordingly, the Court **DENIES** Plaintiffs' sixth motion *in limine*.

G. Motion 7

Plaintiffs anticipate that Breg will attempt to argue or suggest to the jury that it is a "good corporate citizen" that benefits society by making products that are life-saving or improve the

quality of peoples' lives. Plaintiffs argue that such statements have no relevance to the issues before this Court and that the only purpose in making these arguments is to sway the jury into believing that Breg is incapable of irresponsible conduct. Breg argues, *inter alia*, that Plaintiffs' request is premature. This Court agrees.

At this juncture, Plaintiffs cannot provide the Court with enough context to allow it to appropriately determine whether to preclude Breg from referring to evidence of its good acts, especially when such evidence may be relevant to oppose Plaintiffs' punitive damages claims. Consequently, the Court **DENIES** Plaintiffs' seventh motion *in limine*.

H. Motions 8, 9, and 10

In the last three motions, Plaintiffs ask the Court to prohibit Breg from making reference to the results or verdicts in other pain pump litigation, making reference to "lawyer-made" lawsuits, and to painting Plaintiffs' attorneys in a negative light. In its opposition memorandum, Breg indicates that it does not intend to make any such references. Consequently, the Court **DENIES AS MOOT** Plaintiffs' eighth, ninth, and tenth motions *in limine*.

V. Conclusion

Based on the foregoing, the Court **DENIES AND MOOT IN PART AND DENIES IN PART** all ten of Plaintiffs' motions *in limine*. (ECF No. 158.)

IT IS SO ORDERED.

/s/ Gregory L. Frost
GREGORY L. FROST
UNITED STATES DISTRICT JUDGE