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 Breg, Inc.'s Motion *in Limine* to Exclude Documents and Testimony Regarding Actions that Post-Date Pump Usage (ECF Nos. 155, 155-1) and Plaintiffs' Memorandum in Opposition to Breg, Inc.'s Motion *in Limine* to Exclude Documents and Testimony Regarding Actions that Post-Date Pump Usage (ECF No. 162). For the reasons that follow, the Court **GRANTS IN PART AND DENIES IN PART** Breg's motion.

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. Brautigan 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). Consequently, the Court declines to make a definitive pretrial ruling under Federal Rule of Evidence 103(a) as requested by Breg.

III. Federal Rules of Evidence

A. Rules 401 and 402

Federal Rule of Evidence 401provides:

> "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.

C. Rule 407

Federal Rule of Evidence 407 provides:

> When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or

feasibility of precautionary measures, if controverted, or impeachment.

D. Rules 801 and 802

Federal Rule of Evidence 801(c) provides:

> "Hearsay" is a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted.

Federal Rule of Evidence 802 provides:

> Hearsay is not admissible except as provided by these rules or by other rules prescribed by the Supreme Court pursuant to statutory authority or by Act of Congress.

IV. Discussion

Breg moves to exclude documents generated by the Food and Drug Administration ("FDA") and Breg after November 3, 2003, the date of Plaintiff Kaid Musgrave's surgery. Breg argues that those documents are inadmissible under Federal Rules of Evidence 401, 402, 407, 801, and 802, and their admission would prejudice Breg unfairly, justifying exclusion under Rule 403.

Plaintiffs first argue that Breg's motion should be denied because it targets a far-reaching range of documents with little specificity to guide this Court's analysis. Plaintiffs contend that Breg should have specified the particular documents to which it objects rather than shift the burden to this Court and Plaintiffs to sift through thousands of documents in an attempt to guess. Further, Plaintiffs argue that, even if the Court did not deny Breg's request as overbroad, Breg has not met their burden of showing that the evidence is admissible for any purpose. Plaintiffs' arguments are well taken .

As Plaintiffs correctly point out, Breg's request for exclusion is overbroad. Similar to this Court's conclusion regarding overly broad requests for exclusion in *Hinkle v. Norfolk*

Southern Ry. Co., No. 2:05-cv-574, 2007 WL 496365, at *4 (S.D. Ohio, Feb. 12, 2007), the requests here ignore the potential admissibility of the targeted evidence on various grounds, as the Court discusses briefly below. This Court "has the power to exclude evidence *in limine* only when evidence is clearly inadmissible on all potential grounds." *Weimer v. Honda of Am. Mfg.*, No. 2:06-cv-844, 2008 WL 4332525, *1 (S.D. Ohio Sept. 17, 2008) (emphasis added) (citations omitted), aff'd, 356 F. App'x. 812 (6th Cir. 2009) (citing *Luce*, 469 U.S. at 41 n.4). "A court should not make a ruling *in limine* unless the moving party meets its burden of showing that the evidence in question is clearly inadmissible." *Zugovitz v. Davis*, No. 2:06-cv-727, 2008 WL 619357, at *1 (S.D. Ohio Mar. 3, 2008) (citations omitted). Breg's motion in large part fails to satisfy this burden.

A. Internal Breg Documents

Breg anticipates that Plaintiffs will attempt to admit documents that were created after Breg distributed the pain pump used on Kaid Musgrave (*e.g.*, emails, Product Training Documents, Sales Training Documents, and draft "Dear Doctor" letters).

1. Relevance

Plaintiffs offer several reasons why the evidence post-dating Kaid Musgrave's surgery is relevant to their claims and is properly used for impeachment purposes. For example, Plaintiffs' inadequate warning and design defect claims both require a showing of foreseeable risk. *See* Ohio Rev. Code § 2307.76 (inadequate warning); Ohio Rev. Code § 2307.75 (defective design). A risk is foreseeable under the Ohio Product Liability Act, Ohio Revised Code §§ 2307.71-.80, if the manufacturer should have recognized the risk while exercising "the attention, perception, memory, knowledge and intelligence that a reasonable manufacturer should possess" and any

superior information that the manufacturer does possess. Ohio Rev. Code § 2307.71(6)(b). The parties disagree about whether Breg should have known about the risks at issue. Thus, the Court finds that evidence created post-surgery may be relevant to show what Breg should have known at the time of manufacture and distribution, particularly if this evidence indicates that there was information available or information that was actually in possession of Breg during the time of manufacture and/or distribution of the pain pump at issue here. Consequently, the Court cannot say that all of the evidence created post-surgery is irrelevant.

Accordingly, the Court concludes that Breg has failed to meet its burden of showing that the evidence at issue here is clearly inadmissible on all potential grounds.

2. Prejudice

Breg argues that the probative value of post-surgery emails and internal Breg documents is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury. Breg contends that "the jury could confuse the issue of what was known years after the November 2003 surgery with the relevant issue at hand—the issue of what was known or should have been known at the time of the November 4, 2003 surgery." (ECF No. 155-1 at 6.) This Court disagrees. There is nothing in this type of evidence that would be confusing to a jury. Nor is the Court convinced at this time that the probative value of this type of relevant evidence substantially outweighed by a risk of prejudice to Breg.

3. Subsequent Remedial Measures

Breg argues that it "should not be faulted for looking into a possible product issue. Because the emails indicate that Breg employees were discussing and debating their best steps in furtherance of added safety, the emails should not be admitted under Rule 407." (ECF No. 155-1

at 7.) This Court disagrees.

The only remedial measure taken by Breg was to change its product warnings and instructions. Any other conduct referenced in internal communications is not a "measure" for purposes of Rule 407. *See Rocky Mountain Helicopters, Inc. v. Bell Helicopters Textron, a Div. of Textron, Inc.*, 805 F.2d 907, 918-919 (10th Cir. 1986) (noting that "the remedial measure was not the [investigative study] of the [product] but rather the subsequent redesign of the [product]."); *Fasanaro v. Mooney Aircraft Corp.*, 687 F. Supp. 482, 487 (N.D. Cal. 1988) ("By its terms Rule 407 includes only the actual remedial measures themselves and not the initial steps toward ascertaining whether any remedial measures are called for."); *Brett v. Hillerich & Bradsby Co.*, No. CIV-99-2001 U.S. Dist. LEXIS 26320, at *4 (W.D. Okla. Oct. 26, 2001) (the plaintiff may introduce evidence in the form of memoranda and reports, etc., prepared by the defendant subsequent to the incident at issue). Internal communications discussing, for example, the need to conduct animal testing on the safety of anesthetics on joints are not evidence of a remedial measure. They are discussions about proposed plans to study potential causes of an injury, not to remediate a product failure.

Accordingly, Rule 407 does not apply to the emails that discuss what Breg refers to as "a possible product issue." *See Rocky Mountain*, 805 F.2d at 918 ("We hold that the district court did not err in admitting evidence from the Photoelastic Study. It would strain the spirit of the remedial measure prohibition in Rule 407 to extend its shield to evidence contained in post-event tests or reports.").

With regard to the remedial measure taken by Breg to change its product warnings and instructions, that evidence is inadmissible if offered as proof of negligence or culpable

conduct. That evidence, however, may be introduced for other purposes such as to impeach. *See In re Air Crash Disaster*, 86 F.3d 498, 531 (6th Cir. 1996) (noting that Rule 407 does not preclude evidence of subsequent remedial measures offered for purposes of impeachment); Fed. R. Evid. 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.").

B. External Documents

Breg contends that Plaintiffs will likely offer post-distribution documents that were created outside of Breg, such as the two following statements made by the FDA: (1) a November 13, 2009, posting on the FDA's website titled "Information for Healthcare Professionals – Chondrolysis Reported with Continuously Infused Local Anesthetics (marketed as bupivacaine, chlorprocaine, lidocaine, mepivacaine, procaine and ropivacaine)," which includes the following statement: "The FDA has not cleared any infusion devices with an indication for use in intra-articular infusion of local anesthetics."; and (2) a February 2010, posting on FDA's website titled "Chondrolysis with Continuously Infused Local Anesthetics," which includes the statement: "FDA is reminding healthcare professionals that local anesthetics are not approved for intra-articular infusions, or for use in infusion devices like elastomeric pumps. Because of the chondrolysis reports, FDA is requiring the manufacturers of local anesthetic drugs to specifically warn against this use in the products' labeling. A similar warning will be required for elastomeric pumps."

1. Relevance

Breg claims that "the post-distribution FDA statements are not relevant to the issues in

this case because they have no bearing on the questions of Breg's representations, intentions, or whether the Breg Pain Care 3200 was defective at the time of manufacture and distribution." (ECF No. 155-1 at 9.) This Court disagrees.

These post-distribution FDA statements are relevant at least for impeachment purposes. Breg contends that the FDA cleared its pain pumps for intra-articular use. Plaintiffs can present this evidence showing that the FDA had not cleared the pumps for such use. Breg will have an opportunity to present its evidence related to its own interpretation of the documents at issue.

2. Prejudice

Relying on Rule 403, Breg argues that "[t]his evidence also has the potential to mislead the jury and unfairly prejudice Breg." (ECF No. 155-1at 10.) However, as the Sixth Circuit has explained, "[u]nfair prejudice 'does not mean the damage to a defendant's case that results from the legitimate probative force of the evidence; rather it refers to evidence which tends to suggest decision on an improper basis.' " *United States v. Gibbs*, 182 F.3d 408, 430 (6th Cir. 1999) (citations omitted). Here, the Court finds that the probative value of this evidence is not substantially outweighed by the danger of unfair prejudice or jury confusion.

3. Hearsay

Breg argues that the FDA statements are hearsay unredeemed by any recognized hearsay exception. This Court disagrees.

To the extent that the FDA statements at issue are hearsay, the statements fit into the public records exception to the hearsay rule. Public records are admissible hearsay if they are:

> [R]ecords, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the office or agency,or (B) matters observed pursuant to duty imposed by law as to which matters there was a duty to report . . . ., or (C) in civil actions . . . factual findings resulting from an investigation

made pursuant to authority granted by law.

Fed. R. Evid. 803(8).

The FDA bulletins to healthcare professionals state that pain pumps were never cleared for intra-articular use. These portions of the FDA bulletins fall within the hearsay exception defined by Rule 803(8) because they are statements directly from the FDA "setting forth matters observed pursuant to duty imposed by law as to which matters there was a duty to report." Fed. R. Evid. 803(8). As Plaintiffs correctly point out, courts have consistently held that documents like the ones at issue here are admissible. *See, e.g., Toole v. McClintock*, 778 F. Supp. 1543, n.11 (M.D. Ala. 1991) (holding that FDA report on risks of silicone gel breast implants was sufficiently reliable to be admissible hearsay); *Sabel v. Mead Johnson & Co.*, 737 F.Supp. 135 (D. Mass. 1990) (holding that a letter from FDA official recommending that a warning be included on its label was admissible under public records exception to the hearsay rule).

V. Conclusion

Based on the foregoing, the Court **GRANTS IN PART AND DENIES IN PART** Breg, Inc.'s Motion *in Limine* to Exclude Documents and Testimony Regarding Actions that Post-Date Pump Usage. (ECF No. 155.) Specifically, the Court **GRANTS** the motion as it relates to Breg's modifications to the warnings and instructions accompanying its pain pumps and **DENIES** the remainder of the motion. As with all *in limine* decisions, these rulings are subject to modification should the facts or circumstances at trial differ from that which has been

presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

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