IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION	§	MDL Docket No. 3:11-MD-2244-K
This Order Relates To: *Aoki* – 3:13-cv-1071-K *Christopher* – 3:14-cv-1994-K *Greer* – 3:12-cv-1672-K *Klusmann* – 3:11-cv-2800-K *Peterson* – 3:11-cv-1941-K	§	

ORDER DENYING DEFENDANTS' MOTIONS TO DISMISS AND FOR SUMMARY JUDGMENT

Before the Court are the following dispositive motions filed by Defendants:

1. Defendants' Motion for Summary Judgment on Negligent-Misrepresentation Claims [*Aoki* (3:13-cv-1071) Doc. 28, *Christopher* (3:14-cv-1994) Doc. 22, *Greer* (3:12-cv-1672) Doc. 25, *Klusmann* (3:11-cv-2800) Doc. 38, and *Peterson* (3:11-cv-1941) Doc. 39];

2. Defendants' Motion for Partial Summary Judgment as to Plaintiffs' Design-Defect Claims [*Aoki* Doc. 29, *Christopher* Doc. 23, *Greer* Doc. 26, *Klusmann* Doc. 39, and *Peterson* Doc. 40];

3. Defendants' Motion for Summary Judgment as to All Claims Relying on a Theory that DePuy Should Have Sought Premarket Approval or that all Metal-on-Metal Implants are Defective [*Aoki* Doc. 31, *Christopher* Doc. 25, *Greer* Doc. 28, *Klusmann* Doc. 41, and *Peterson* Doc. 42];

4. Defendants' Motion for Summary Judgment on Claims Sounding in Failure to Warn, Misrepresentation or Omission [*Aoki* Doc. 33, *Greer* Doc. 30, *Klusmann* Doc. 43, and *Peterson* Doc. 44];

5. Defendants Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International, and DePuy Synthes, Inc.'s Motion to Dismiss for Lack of Personal Jurisdiction or, in the Alternative, Motion for Summary Judgment [*Aoki* Doc. 37, *Christopher* Doc. 30, *Greer* Doc. 34, *Klusmann* Doc. 48, and *Peterson* Doc. 48]; and

6. Defendants' Motion for Summary Judgment on Plaintiffs' Claims for Tortious Interference with the Physician-Patient Relationship and Vicarious Liability for Breach of Fiduciary Duty and Their Request to Set Aside the Statutory Cap on Exemplary Damages [*Aoki* Doc. 40, *Klusmann* Doc. 51, and *Peterson* Doc. 51].

For the reasons set forth herein, the motions are DENIED.

I. Factual and Procedural Background

Pursuant to 28 U.S.C. § 1407, the United States Judicial Panel on Multidistrict Litigation ordered coordinated or consolidated pretrial proceedings in this Court of all actions involving the Pinnacle Acetabular Cup System hip implants ("Pinnacle Device") manufactured by Defendant DePuy Orthopaedics, Inc. The DePuy Pinnacle multidistrict litigation ("MDL") involves the design, development, manufacture, and distribution of the Pinnacle Device. The Pinnacle Device is used to replace diseased hip joints and was intended to remedy conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture, and to provide patients with pain-free natural motion over a longer period of time than other hip replacement devices. Presently there are over eight thousand cases in this MDL involving Pinnacle Devices made with sockets lined with metal, ceramic, or polyethylene. The Plaintiffs in the MDL act through a large group of Plaintiffs' lawyers that form the Plaintiffs' Steering Committee, which in turn is headed by the Plaintiffs' Executive Committee, a small group from the Plaintiffs' Steering

Committee appointed by this Court to conduct discovery and other pretrial proceedings and identify common issues in the MDL.

Pursuant to an Order of this Court, the *Aoki*, *Christopher*, *Greer*, *Klusmann*, and *Peterson* matters were selected as bellwether matters to be prepared for trial. The Plaintiffs in these matters are five Texas residents who received a Pinnacle Ultamet hip implant. They assert claims for strict liability, negligence, negligent misrepresentation, fraud, and breach of express and implied warranties against Defendants as a result of the failure of their implants and subsequent replacements. Defendants' Motions seek to dismiss certain causes of action alleged by Plaintiffs. In a prior Order, this Court dismissed pursuant to Rule 12(b)(6) Plaintiffs' claims for fiduciary duty based on Dr. Heinrich's alleged failure to disclose his status as a retained expert. Accordingly, the request to dismiss the same on summary judgment is DENIED as moot. The remainder of Defendants' motions to dismiss and for summary judgment are addressed herein.

II. Burden of Proof

A. Motion to Dismiss

When a non-resident challenges personal jurisdiction under Rule 12(b)(2) of the Federal Rules of Civil Procedure, this Court makes a two-step inquiry in determining whether there is personal jurisdiction. *Gartin v. Par Pharm. Cos., Inc.*, 561 F. Supp. 2d 670, 674 (E.D. Tex. 2007), *aff'd*, 289 Fed. Appx. (5th Cir. 2008). First, this Court determines whether the long-arm statute of the forum state permits the exercise of jurisdiction. *Id.* Second, this Court determines whether the exercise of

jurisdiction comports with due process. *Id.* Here, the forum state is Texas, and Fifth Circuit law applies for the due process analysis. *Id.* In this case, these two steps merge into a single analysis because Texas' long-arm statute has been construed to allow the exercise of personal jurisdiction over nonresidents to the maximum extent permitted by federal due process. *Luv N' care, Ltd. v. Insta-Mix, Inc.*, 438 F.3d 465, 469 (5th Cir. 2006).

The Due Process Clause permits the exercise of personal jurisdiction over a non-resident when (1) the defendant has established minimum contacts with the forum state and (2) the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice. *Kelly v. Syria Shell Petroleum Dev't, B.V.*, 213 F.3d 841, 854 (5th Cir. 2000). The minimum contacts requirement can be established through specific or general jurisdiction. *Id.* Specific jurisdiction is appropriate when a non-resident corporation has purposefully directed its activities at the forum state and the litigation results from alleged injuries that arise out of or relate to those activities. *Id.* General jurisdiction exists when the non-resident defendant's contacts with the forum state are continuous and systematic although not necessarily related to the litigation. *Id.*

B. Summary Judgment

This Court shall grant summary judgment if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). An issue as to a material fact is genuine if a

reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). This Court considers all evidence in the light most favorable to the party resisting the motion. *Trevino v. Celanese Corp.*, 701 F.2d 397, 407 (5th Cir. 1983).

III. Analysis

A. Negligent Misrepresentation Claims

Defendants DePuy Orthopaedics, Inc. and DePuy Products, Inc. ("DePuy" or "Defendants") move for summary judgment on Plaintiffs' claims for negligent misrepresentation. Defendants Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International, and DePuy Synthes, Inc. ("the Johnson & Johnson Defendants") filed a separate motion to dismiss for lack of personal jurisdiction or, in the alternative, for summary judgment, which is addressed below. The Johnson & Johnson Defendants "only join [DePuy's motions] to the extent their separate motion to dismiss is denied." DePuy contends that Plaintiffs' claims fail as a matter of law, as they have not alleged they were negligently advised in a business transaction. Plaintiffs, on the other hand, contend that no such requirement applies.

Under Texas law, the traditional elements for negligent misrepresentation are that (1) the representation is made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest; (2) the defendant supplies "false information" for the guidance of others in their business; (3) the defendant did not exercise reasonable care or competence in obtaining or communicating the

information; and (4) the plaintiff suffers pecuniary loss by justifiably relying on the representation. *Fed. Land Bank Ass'n of Tyler v. Sloane*, 825 S.W.2d 439, 442 (Tex. 1991). Plaintiffs do not contest that any misrepresentations at issue fall outside of the "business transaction" context. Rather, they observe that Texas courts have recognized that actionable negligent misrepresentations may occur outside of the business context, particularly in the case of professional negligence. *See, e.g.*, *Cook Consultants, Inc. v. Larson*, 700 S.W.2d 231, 233-26 (Tex. App.—Dallas 1985, writ ref'd n.r.e.) (surveyor that was hired by builder was liable to homeowner for surveyor's negligent misrepresentation). When viewed in the light most favorable to Plaintiffs, the Court finds that a reasonable jury could return a verdict for the Plaintiffs.

Defendants' Motion for Summary Judgment on Negligent-Misrepresentation Claims [*Aoki* Doc. 28, *Christopher* Doc. 22, *Greer* Doc. 25, *Klusmann* Doc. 38, and *Peterson* Doc. 39] is DENIED.

B. Design Defect Claims

DePuy moves for partial summary judgment on all claims sounding in design defect theories, including each "Strict Liability – Design Defect" cause of action and claims for negligence and breach of implied warranty of merchantability. DePuy contends that these state law claims are preempted by federal law under the Supreme Court's holding in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2580-81 (2011) due to an impossible conflict between state and federal law, as the Pinnacle Device is subject to

federal regulation and no change can be made to the design of a device without FDA permission.

Plaintiffs seek to recover from DePuy in strict liability based on allegations that the metal-on-metal Pinnacle Device is unreasonably dangerous for its intended purpose and, therefore, defective. DePuy alleges that the state and federal law applicable in this case conflict because it is impossible for it to independently comply with both state and federal requirements. DePuy, therefore, argues that the state law claims are preempted under *Mensing*. The *Mensing* matter involved the preemption of failure-to-warn claims for generic prescription drugs; the FDA must pass on the safety of drugs and the accompanying warnings before a drug can be marketed, and liability must be predicated only on the manufacturer's ability to unilaterally make changes after government approval of the warning. *Id.* DePuy asks this Court to extend the holding of *Mensing* to medical devices such as the Pinnacle Device. The Court declines to do so and finds that the Supreme Court's decision in *Medtronic, Inc. v. Lohr* is controlling. 518 U.S. 470 (1996). *Lohr* specifies that for medical devices cleared for use by the FDA using the Section 510(k) process, such as the Pinnacle Device, there is no preemption under the Medical Device Act ("MDA"). *Id.* at 493-94. This is because, unlike the medication warnings at issue in *Mensing*, the MDA imposes no design requirements on the manufacturer. *See id.*

The undisputed summary judgment evidence shows that like the device at issue in *Lohr*, the Pinnacle Device was cleared through the section 510(k) process

(rather than the alternative of premarket approval). The FDA never passed on the original design of the device and imposed no requirements for safety or otherwise on it. The FDA merely determined whether the Pinnacle Device was substantially equivalent to a grandfathered device. DePuy, therefore, could not have been subject to conflicting state and federal design requirements that would give rise to preemption.

Defendants' Motion for Partial Summary Judgment as to Plaintiffs' Design-Defect Claims [*Aoki* Doc. 29, *Christopher* Doc. 23, *Greer* Doc. 26, *Klusmann* Doc. 39, and *Peterson* Doc. 40] is DENIED.

C. Premarket Approval/Metal-on-Metal Defect Claims

DePuy moves for summary judgment on all claims to the extent they rely on evidence or argument that (1) defendants should have sought premarket approval instead of relying on the § 510(k) substantial-equivalence clearance process; or (2) all metal-on-metal hip implants are inherently defective. DePuy contends that these claims are preempted by federal law. First, DePuy contends that the FDA has the exclusive authority to determine what submissions should be made to that agency to receive clearance to market a drug, and Plaintiffs' position that DePuy should have used the alternate, more rigorous clearance process interferes with the FDA's authority. Second, DePuy also contends that any claim that metal-on-metal devices are inherently defective is contrary to the FDA's decision to permit such devices and is preempted under the MDA.

Generally speaking, product manufacturers have two options when seeking product approval from the FDA: a pre-market approval ("PMA") process, and a substantial equivalence "grandfathering" standard (the "510(k)" process). As both Plaintiffs and Defendants acknowledge, both procedures are lawful mechanisms for obtaining FDA approval. Accordingly, DePuy contends that any causes of action which contend that DePuy should have used the more rigorous PMA process are preempted, as they interfere with the FDA's authority to determine its own clearance procedures. However, as explained above, there is a significant difference in the effects of the PMA and 510(k) processes; products undergoing the PMA process are preempted from claims under state law as to the design and manufacture of the product where products undergoing the 501(k) process are not. While DePuy had the right to proceed under the 501(k) process, nothing in the law permits that process to be used as a shield against inquiry regarding the approval process.

DePuy also contends that any claim that metal-on-metal devices are inherently defective is contrary to the FDA's decision to permit such devices and is preempted under the MDA. Generally speaking, common law claims regarding medical devices that have received a PMA from the FDRA are preempted. *Riegel v. Medtronic, Inc.*, 522 U.S. 312 (2008). However, this preemption applies specifically to items cleared through the rigorous PMA process. As noted by Plaintiffs, the FDA has approved three "hip resurfacing implants" under the PMA process. *See Christiansen v. Wright Med. Tech., Inc.*, 2015 U.S. Dist. LEXIS 15601 *4 (August 31, 2015). The PMA

process is specific to individual devices, however, and so is PMA preemption. The fact that a different metal-on-metal device has been approved does not preclude claims that the products at issue are defective and cannot support an argument that such claims are preempted. *Id.* at *112-13.

Defendants' Motion for Summary Judgment as to All Claims Relying on a Theory that DePuy Should Have Sought Premarket Approval or that all Metal-on-Metal Implants are Defective [*Aoki* Doc. 31, *Christopher* Doc. 25, *Greer* Doc. 28, *Klusmann* Doc. 41, and *Peterson* Doc. 42] is DENIED.

D. Failure to Warn, Misrepresentation, or Omission Claims

DePuy moves for summary judgment on Plaintiffs' claims sounding in failure to warn, misrepresentation, or omission. Specifically, DePuy contends that it is entitled to summary judgment on Plaintiffs' claims for under theories of failure to warn, fraud, or breach of express warranty, because Plaintiffs cannot prove a causal connection between DePuy's representations and the alleged injuries. In other words, DePuy contends Plaintiffs cannot meet their burden to demonstrate that their surgeons relied on DePuy's statements in using the Pinnacle Ultamet or that a different representation or warning would have prevented their surgeons from using the Pinnacle Ultamet.

DePuy contends first that Plaintiffs Aoki, Greer, Klusmann, and Peterson cannot meet their burden under Texas law that a different warning would have affected their surgeons' decisions to use the Pinnacle Ultamet or that their surgeons

relied on any marketing material from DePuy. Plaintiff Christopher's claims are not a subject of this Motion. Under Texas law, a plaintiff alleging failure to warn "must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury." *See Ebel v. Eli Lilly & Co*, 321 F. App'x 350, 355 (5th Cir. 2009). A plaintiff alleging common-law fraud, statutory fraud or negligent misrepresentation must also prove causation, or that the party acted in reliance upon the representation or warranty at issue. *See, e.g.*, *Diamond Offshore Co. v. Survival Sys. Int'l, Inc.*, 902 F. Supp. 2d 912, 930-31 (S.D. Tex. 2012); *Ackermann v. Wyeth Pharm.*, 471 F. Supp. 2d 739, 744 (E.D. Tex. 2006), *aff'd*, 526 F.3d 203 (5th Cir. 2008). Under the "learned intermediary" doctrine, applicable in Texas, a manufacturer's duty to warn of alleged risks runs to the treating physician, not the patient. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999).

DePuy contends that the evidence shows that Plaintiffs' physicians did not rely on DePuy's marketing materials, as the physicians testified that they either did not read or did not give weight to advertisement and instead conducted their own research. DePuy argues, therefore, that Plaintiffs cannot prove causation or reliance in these claims.

The summary judgment evidence viewed in the light most favorable to Plaintiffs shows:

1. Dr. Schoch is the implanting physician for Plaintiff Peterson. Dr. Schoch's awareness of the Pinnacle Ultamet came primarily from Defendants' sales

force, and Dr. Schoch obtained information from—and relied on—the scientific and medical information the sales representative provided to him.

2. DePuy paid doctors to market and present DePuy products through what appeared to be neutral, even peer-reviewed sources such as continuing medical education, lectures, and articles, including presentations at conferences regularly attended by Dr. Schoch and dinners attended by Dr. Schoch which would appear as independent research to physicians.

3. Dr. Heinrich, the implanting physician for Plaintiff Aoki and Plaintiff Klusmann reviewed and relied upon information from Defendants' sales representatives, was called on by numerous sales representatives, and relied upon data provided to him by the sales representative such as aSPHERE simulator data which was developed under pressure and with a purpose of boosting sales.

4. Dr. Henrich read the Instructions for Use ("IFU") accompanying the Pinnacle Ultamet.

5. DePuy placed advertisements and other sales pieces in medical journals, brochures, and other materials in order to market DePuy's messages as scientific reports and publications to physicians.

6. DePuy made false claims regarding the wear rates, fluid film lubrication, and survivorship of the Pinnacle Device through its satellite presentation, paid consultants, continuing medical education seminars, and published articles.

7. Dr. Schoch and Dr. Heinrich each made their decisions to use the Pinnacle Device based at least in part in reliance on advertising claims made by DePuy.

8. Dr. Schoch was never informed but would have wanted to know that the Ultamet's predecessor was taken off the market in Europe, that Defendants' simulator testing showed catastrophic breakdown and large volumes of wear debris, no fix existed for the poor component design and tolerancing evidenced by simulator testing, old generation metal-on-poly implants had a better survivorship record than the Ultamet, and that internal documents acknowledged risks of implant longevity, corrosion of metal components, local or systemic immunologic reaction to prosthetic implant or particulate debris, cancer, early or long-term increased serum, urine and tissue levels of metal ions, and bone resorption caused by particulate wear debris from the implant.

Had Dr. Schoch been informed of such problems he would not have used the Ultamet or would have at least discussed these warnings with his patient.

9. Likewise, Dr. Heinrich testified that Defendants' information influenced his treatment decision and, had he been provided with knowledge regarding the treatment of pain complaints following the implantation of the Ultamet, it would have changed his treatment of Plaintiff Klusmann. Dr. Heinrich was willing to alter his treatment decisions when Defendants shared their knowledge with him, but Defendants hid their master surgeons' knowledge regarding catastrophic failure of the Ultamet device and decisions to stop using metal-on-metal devices from Dr. Heinrich.

10. The information about the risks and adverse reports of the Ultamet caused Drs. Schoch and Heinrich to stop implanting the device in their patients.

11. No reasonable physician would have implanted a patient with a metal-on-metal device if all information known by DePuy had been disclosed to them.

12. In the course of his relationship with DePuy, Dr. Heinrich has agreed not to sell, evaluate, or promote non-DePuy products and to cooperate fully with DePuy in the handling of the claim or defense of any product liability litigation. At one time, Dr. Heinrich participated in a "kickback scheme" with Defendants, and currently serves as an expert for Defendants.

13. Dr. Goletz, the implanting surgeon for Plaintiff Greer, has received from DePuy thousands of dollars in Honorariums, reimbursements, royalties, and payments for speaking engagements and promotional speaking events, and has been identified by Defendants as a "Key DePuy Surgeon."

14. Plaintiffs Aoki, Greer, Klusmann, and Peterson would not have consented to the implantation of the Ultamet device if they had been warned about its true risks.

Considering all this evidence, this Court finds with respect to Plaintiffs Aoki, Klusmann, and Peterson that a reasonable jury could determine that Drs. Schoch and Heinrich relied upon DePuy's misrepresentations and omissions concerning the Pinnacle Device and would have acted differently had Defendants been transparent

about the true risks of the Ultamet, satisfying the burden under the learned intermediary doctrine.

Moreover, the learned intermediary doctrine does not apply when a manufacturer compensates a physician or incentivizes him or her to use its product. *Murthy v. Abbott Labs*, 847 F. Supp. 2d 958, 971-73 (S.D. Texas 2012). Because of the relationship between DePuy and Drs. Goletz and Heinrich, a fact question exists regarding the legitimacy and objectiveness of Drs. Goletz and Heinrich that precludes application of the learned intermediary doctrine as a basis for summary judgment. Additionally, with respect to Plaintiffs Aoki, Greer, Klusmann, and Peterson, there is a fact issue precluding summary judgment as to the Plaintiffs' own treatment choices had the risks been disclosed. While a manufacturer may usually rely on the learned intermediary doctrine in satisfying its duty to warn, such reliance is not reasonable when the intermediary does not pass on necessary information due to the manufacturer's understatement of the risk. *See McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2007). Plaintiffs contend that they would not have consented to the implant if they had been warned about the Ultamet's true risk, and accordingly, fact issues exist as to the application of the learned intermediary doctrine and the resulting duty to warn.

Defendants' Motion for Summary Judgment on Claims Sounding in Failure to Warn, Misrepresentation or Omission [*Aoki* Doc. 33, *Greer* Doc. 30, *Klusmann* Doc. 43, and *Peterson* Doc. 44] is DENIED.

E. Lack of Personal Jurisdiction or, Alternatively, Summary Judgment

Personal Jurisdiction

The Johnson & Johnson Defendants contend this case should be dismissed against them under rule 12(b)(2) of the Federal Rules of Civil Procedure because this Court lacks personal jurisdiction over them. The Johnson & Johnson Defendants contend that they have no contacts with Texas that would support the exercise of personal jurisdiction. None of the Johnson & Johnson Defendants are incorporated or have their principal place of business in Texas, and all are holding/parent companies or service providers that do not manufacture, distribute, or sell products like the Pinnacle Device. Johnson & Johnson International is a subsidiary of Johnson & Johnson; DePuy Synthes, Inc. is a subsidiary of Johnson & Johnson International; and DePuy, the manufacturer and seller of the Pinnacle Device, is a subsidiary of DePuy Synthes, Inc. Johnson & Johnson Services, Inc. provides services to various Johnson & Johnson subsidiaries, and those services are paid for by the subsidiaries. As such, they contend that they lack contacts with either forum and this Court should dismiss the claims against them for want of personal jurisdiction.

The evidence shows that the Johnson & Johnson Companies (1) hosted a nationwide satellite telecast to physicians all over the country, including Texas, to tout the advantages of the Pinnacle Device, including representations of the benefits of metal-on-metal hip replacements and fluid film lubrication that are in issue in this case; (2) gave direction regarding advertising content and appearance for the Pinnacle

Device; (3) managed the recall of another implant device and redirecting customers to the Pinnacle line; (4) made a website available to DePuy for doctors and patients and anyone else seeking information to view advertisements about the Pinnacle Device; and (5) placed their name on all Pinnacle Device advertising, literature, products, and packaging that contained representations that are in issue in this case and that were distributed across the country, including in Texas, for health care providers and doctors to see.

Plaintiffs' claims against the Johnson & Johnson Defendants include fraud-based claims arising from their involvement in the alleged formulation and dissemination of a campaign of misinformation regarding the safety of the Pinnacle Device. The Fifth Circuit has held that the distribution of false information to consumers within a state will subject a defendant to the jurisdiction of the courts of that state. *Guidry v. United States Tobacco Co., Inc.*, 188 F.3d 619, 628 (5th Cir. 1999). The evidence in this case is sufficient to establish minimum contacts through specific jurisdiction by the Johnson & Johnson Defendants' marketing activities with respect to the Pinnacle Device. The Johnson & Johnson Defendants do not assert in their motion to dismiss that the exercise of jurisdiction over them in this case offends traditional notions of fair play and substantial justice. Accordingly, this Court need not address that issue

Summary Judgment

In the event this Court finds jurisdiction over them, the Johnson & Johnson Defendants move for summary judgment on all of Plaintiffs' causes of action against them, which they categorize as either product liability claims (negligence, strict liability, breach of express and implied warranties) or fraud claims (negligent misrepresentation, intentional misrepresentation, and fraudulent concealment). First, they contend that the product liability claims fail because none of the Johnson & Johnson Defendants manufactured or sold the Pinnacle Device. Second, they argue that the fraud claims fail because Plaintiffs have not identified any misrepresentation that the Johnson & Johnson Defendants made upon which Plaintiffs relied.

Products Liability

First, Defendants contend that the product liability claims against the Johnson & Johnson Defendants fail because none of the Johnson & Johnson Defendants manufactured or sold the Pinnacle Device. Under Texas law, strict liability claims may only be brought against a defendant that "designed, manufactured or sold the products in question." *Ruiz v. Whirlpool, Inc.*, No. CIV. A. SA-90-CA-689, 1992 WL 566626, at *5 (W.D. Tex. Aug. 26, 1992), *aff'd*, 12 F.3d 510 (5th Cir. 1994). Negligence based claims require a plaintiff to establish that a defendant owed them a duty of care, which Texas law only extends to manufacturers or sellers in the product-liability context. *See, e.g.*, *id.* at *5. Only a "seller" of goods may be held liable under a theory of breach of warranty. *See* Tex. Bus. & Com. Code Ann. §§ 2.313, 2.314.

Under Texas law, a "seller" is "a person who is engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption a product or any component part thereof. Tex. Civ. Prac. & Rem. Code §82.001(3). A non-manufacturing seller is liable for harm if "the seller participated in the design of the product," *id.* §82.003(a)(1), or if "the seller actually knew of a defect to the product at the time the seller supplied the product" and "the claimant's harm resulted from the defect." *Id.* §82.003(a)(6).

Taking the evidence in the light most favorable to Plaintiffs, the summary judgment record indicates that the Johnson & Johnson Defendants granted DePuy "clearance" to manufacture, use, and sell the product, approved or vetoed DePuy's sales materials, oversaw DePuy's electronic and print advertising campaign for the Pinnacle Device, allowed the "Johnson & Johnson" name to be placed on all advertising to provide strength to the DePuy brand, and continued to do each of these things following reports of defect. The summary judgment record also indicates that the Johnson & Johnson Defendants sponsored a nationwide telecast and website for the purpose of promoting Pinnacle devices. The Court finds that a reasonable jury could determine that the Johnson & Johnson Defendants engaged in distributing or placing the Pinnacle Device into the stream of commerce, participated in the design of the product or actually knew of a defect to the product at the time of supplying the product supplied the product, and that Plaintiffs' harm resulted from the defect.

Fraud

Second, the Johnson & Johnson Defendants argue that the fraud claims fail because Plaintiffs have not identified any misrepresentation that the Johnson & Johnson Defendants made upon which Plaintiffs relied. *See, e.g.*, *Grant Thornton LLP v. Prospect High Income Fund*, 314 S.W.3d 913, 923 (Tex. 2008). However, when taken in the light most favorable to the Plaintiffs, the summary judgment record raises issues with respect to the truthfulness of the fluid film lubrication theory that was introduced at the Johnson & Johnson organized and sponsored satellite broadcast to over 1500 physicians in 86 different locations, the truthfulness of numerous statements in DePuy's advertising materials and literature over which the Johnson & Johnson Companies had authority or sponsored, such as the 99.9% five-year survival rate, and the knowledge and concealment of device failures which DePuy was claiming as a substantially equivalent device to the Pinnacle Device. As fully discussed with Defendants' previous summary judgment motions, there is also sufficient summary judgment evidence to raise a fact issue regarding the reliance of Plaintiffs and their physicians on these representations.

Defendants Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International, and DePuy Synthes, Inc.'s Motion to Dismiss for Lack of Personal Jurisdiction or, in the Alternative, Motion for Summary Judgment [*Aoki* Doc. 37, *Christopher* Doc. 30, *Greer* Doc. 34, *Klusmann* Doc. 48, and *Peterson* Doc. 48] is DENIED.

F. Tortious Interference with the Physician-Patient Relationship, Vicarious Liability for Breach of Fiduciary Duty, and Request to Set Aside Statutory Cap on Exemplary Damages

Finally, DePuy moves for summary judgment on (1) Plaintiffs' claims for tortious interference with the physician-patient relationship; (2) Plaintiffs' claims for vicarious liability for breach of fiduciary duty; and (3) Plaintiffs' claims for relief from the Texas cap on exemplary damages based on their allegation of commercial bribery. DePuy's contentions with respect to the unavailability of the claims for tortious interference and vicarious liability were addressed by this Court in a previous Order with respect to the standards under Rule 12(b)(6) of the Federal Rules of Civil Procedure; the Court will address each of the remaining claims now under a summary judgment standard.

Tortious Interference

First, DePuy moves for summary judgment on Plaintiffs Klusmann and Peterson's claims for tortious interference with the physician-patient relationship with respect to orthopedic surgeon Eric Heinrich. Since 2005, Dr. Heinrich has served in various consulting and promotional roles for DePuy, including contractual consulting agreements where Dr. Heinrich agreed to exclusively perform such services for DePuy. After beginning his relationship with DePuy, Dr. Heinrich performed implant surgery on Plaintiff Klusmann and later performed revision surgeries for both Plaintiff Klusmann and Plaintiff Peterson. Dr. Heinrich was subsequently retained as

an expert by Defendants in this MDL, and at that time, DePuy instructed Plaintiffs to have no direct communication with Dr. Heinrich.

To prevail on their tortious interference claims, Plaintiffs must prove that (1) Plaintiffs entered an enforceable contract with Dr. Heinrich; (2) Defendants willfully interfered with that contract; (3) Defendants' interference proximately caused Plaintiffs' damages; and (4) Plaintiffs suffered actual damage or loss. *See Butnaru v. Ford Motor Co.*, 84 S.W.3d 198, 207 (Tex. 2002). Defendants do not contest the first element. Viewing the summary judgment evidence in the light most favorable to Plaintiffs, the record indicates that Dr. Heinrich was provided lucrative contracts—including compensation for hundreds of thousands of dollars—based on his relationship with DePuy, that Dr. Heinrich promoted Defendants' materials to Plaintiffs based upon Defendants' promotional materials, that, due to DePuy's official position on the efficacy of the metal-on-metal devices, delayed appropriate intervention in Plaintiff Klusmann's care and concealed indications of particle disease or elevated metal levels from Plaintiff Peterson, that Plaintiffs were instructed by Defendants from contacting Dr. Heinrich after he was designated as an expert, and that as a result of DePuy's interference in their relationship with Dr. Heinrich, Plaintiffs experienced increased pain and suffering from treatment delays as well as the inconvenience of finding a new doctor. The Court finds that a reasonable jury could find that Defendants tortuously interfered with Dr. Heinrich's physician-patient relationships with Plaintiff Klusmann and Plaintiff Peterson.

Vicarious Liability on Breach of Fiduciary Duty

DePuy also moves for summary judgment on the claim for vicarious liability as to Dr. Heinrich's breach of fiduciary duty. Plaintiffs contend that at all relevant times, Dr. Heinrich served as an agent for Defendants, and in the course of that agency, breached fiduciary duties owed to Plaintiffs through serving as an expert witness for Defendants and by using confidential information obtained in his treatment of plaintiffs to aid defendants in litigation. Plaintiffs' claim for breach of fiduciary duty based on failure to disclose a conflict of interest in his consulting relationship with Defendants has been dismissed with prejudice in a prior Order. Under Texas law, a principal is vicariously liable for the torts of its agent committed in the course and scope of his employment. *Hopkins v. Wells Fargo Bank, N.A.*, 3:10-CV-1857-D, 2011 WL 611664, at *3 (N.D. Tex. Feb. 28, 2011). Through Defendants' agreements with Dr. Heinrich, they retained the right to exercise control over all Dr. Heinrich's professional activities with respect to Defendants' products, including limiting the services Dr. Heinrich could perform and retaining control over the substance of Dr. Heinrich's opinions and evaluations regarding Defendants' products. Defendants also employed Dr. Heinrich to promote its products and assist with the defense of product liability claims. As such, sufficient evidence exists from which a reasonable jury could make a finding of agency. *See, e.g., Limestone Prods. Distrib., Inc. v. McNamara*, 71 S.W.3d 308, 312 (Tex. 2002).

Generally, a physician owes his or her patient a fiduciary duty, including the duties of loyalty and utmost good faith, the duty of candor, and the duty of full disclosure. *Kinzbach Tool Co. v. Corbett-Wallace Corp.*, 160 S.W.2d 509, 512-13 (Tex. 1942). The elements of a fiduciary duty claim are: (1) a fiduciary relationship between the plaintiff and defendant; (2) breach of that fiduciary duty; and (3) injury to the plaintiff or benefit to the defendant. *Jones v. Blume*, 196 S.W.3d 440, 447 (Tex. App.—Dallas 2006, pet. denied). Plaintiffs allege that Dr. Heinrich, in acting as an agent for Defendants breached his fiduciary duty by (1) failing to disclose his role as an expert while consulting with Defendants to defeat Plaintiffs' claims; (2) voluntarily serving as a retained expert witness in litigation directly related to Dr. Heinrich's treatment of Plaintiffs; and (3) breaching his duty of confidentiality and trust by using Plaintiffs' confidential and privileged medical records to aid in his role as expert witness. As explained in full in this Court's Order regarding Defendants' motion to dismiss this claim under Rule 12(b)(6), this Court declines to recognize a breach of fiduciary duty arising from a failure to disclose a consulting relationship.

The Plaintiffs also assert that Dr. Heinrich breached his duty of loyalty through serving as a retained expert witness in litigation directly related to Dr. Heinrich's treatment of Plaintiffs and breached his duty of confidentiality and trust by using Plaintiffs' confidential and privileged medical records to aid in his role as expert witness, including engaging in discussions with defense counsel regarding Plaintiffs. In essence, Plaintiffs contend that through his service as a consulting

expert in this bellwether, Dr. Heinrich could not have fulfilled his fiduciary duties to Plaintiff because it would be impossible for him to "act solely for the benefit" of the Plaintiffs in all matters connected with their fiduciary relationship. *See Nat'l Plan Adm'rs, Inc. v. Nat'l Health Ins. Co.*, 235 S.W.3d 695, 700 (Tex. 2007). The summary judgment record indicates that Dr. Heinrich has, in his experience as a testifying expert in the previous bellwether in this MDL, used and referred to the medical records of his patients, including Plaintiffs, as support for his expert testimony for Defendants. A sufficient issue of fact exists as to whether this conduct violated duties of loyalty or confidentiality and trust.

Exemplary Damage Limit

Finally, Defendants seek summary judgment on Plaintiffs' request to set aside the cap on exemplary damages, as they contend there is no evidence to support an allegation of commercial bribery. Under the Texas Civil Practice and Remedies Code, the ordinary limitation on the amount of exemplary damages available does not apply where the cause of action is based on certain felony conduct identified in the Texas Penal Code. Tex. Civ. Prac. & Rem. Code § 41.008(c)(9). Here, Plaintiffs Aoki, Klusmann, and Peterson contend that the applicable limitation should be set aside, as Defendants have supposedly engaged in commercial bribery, a felony under Section 32.43 of the Texas Penal Code. Defendants move for summary judgment on the basis that Dr. Heinrich was not influenced in the treatment of his patients due to any consulting agreements, and even if his conduct was influenced generally, there is no

evidence that Defendants knew Dr. Heinrich's conduct would be influenced with respect to these specific Plaintiffs or that any such conduct was connected to their injuries.

Commercial bribery occurs when a person offers, confers, or agrees to confer any benefit to a fiduciary with an agreement or understanding that the benefit will influence the conduct of the fiduciary in relation to the affairs of his beneficiary. Tex. Penal Code § 32.43. To set aside the cap on exemplary damages, Plaintiffs must demonstrate that the Defendants knowingly or intentionally offered, conferred, or agreed to confer a benefit to Dr. Heinrich with an agreement or understanding that the benefit would influence the conduct of Dr. Heinrich in relation to the affairs (or treatment) of his patients. The record indicates that DePuy entered into a Deferred Prosecution Agreement in September 2007 relating to allegations concerning the Federal Anti-Kickback Statute and compensation made to consultants with the end goal of driving sales through those paid consultants. Dr. Heinrich had a financial consulting relationship with Defendants as early as 2005, disproportionately used Defendants' products over other manufacturers, and continued to use the Pinnacle Device after other surgeons had stopped. Construing this evidence in the light most favorable to Plaintiffs, a fact issue exists precluding summary judgment on the application of exemplary damage limitations.

Defendants' Motion for Summary Judgment on Plaintiffs' Claims for Tortious Interference with the Physician-Patient Relationship and Vicarious Liability for

Breach of Fiduciary Duty and Their Request to Set Aside the Statutory Cap on Exemplary Damages [*Aoki* Doc. 40, *Klusmann* Doc. 51, and *Peterson* Doc. 51] is DENIED.

IV. Conclusion

Defendants have pointed out numerous issues with respect to Plaintiffs' claims in this case. This Court finds, however, that for purposes of summary judgment, the evidence when viewed in the light most favorable to Plaintiffs raises fact issues such that a reasonable jury could return a verdict for Plaintiffs. Defendants' motions to dismiss and for summary judgment are DENIED.

SO ORDERED.

Signed January 5th, 2016.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE