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.
This Order Relates To:	§	
Andrews – 3:15-cv-03484-K	§	
Davis – 3:15-cv-01767-K	§	3:11-MD-2244-K
Metzler – 3:12-cv-02066-K	§	
Rodriguez – 3:13-cv-3938-K	§	
Standerfer – 3:14-cv-01730-K	§	
Weiser – 3:13-cv-03631-K	§	

ORDER DENYING DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

Before the Court are the following motions:

1. Johnson & Johnson, Johnson & Johnson Servs., Inc., Johnson & Johnson Int'l, and DePuy Synthes, Inc.'s Motion for Summary Judgment [*Andrews* Doc. 65; *Davis* Doc. 70; *Metzler* Doc. 66; *Rodriguez* Doc. 65; *Standerfer* Doc. 68; and *Weiser* Doc. 71];

2. Defendants' Motion for Partial Summary Judgment as to Plaintiffs' Design-Defect Claims [*Andrews* Doc. 68; *Davis* Doc. 71; *Metzler* Doc. 67; *Rodriguez* Doc. 66; *Standerfer* Doc. 69; and *Weiser* Doc. 72];

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 [*Andrews* Doc. 73; *Davis* Doc. 72; *Metzler* Doc. 68; *Rodriguez* Doc. 67; *Standerfer* Doc. 70; and *Weiser* Doc. 73];

4. Defendants' Motion for Summary Judgment as to Plaintiffs' Claims Sounding in Failure to Warn and Fraud [*Andrews* Doc. 69; *Davis* Doc. 73; *Metzler* Doc. 69; *Rodriguez* Doc. 68; *Standerfer* Doc. 71; and *Weiser* Doc. 74]; and

5. Defendants' Motion for Partial Summary Judgment as to Plaintiffs' Warranty Claims [*Andrews* Doc. 70; *Davis* Doc. 74; *Metzler* Doc. 70; *Rodriguez* Doc. 69; *Standerfer* Doc. 72; and *Weiser* Doc. 75].

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. ("DePuy"). 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.

Over the pendency of this MDL, the Court has held two prior bellwether trials, the first in September and October 2014 involving a Montana Plaintiff and her husband (the "*Paoli*" bellwether, No. 3:12-cv-04975-K), and the second in January through March 2016, consolidating five cases brought by Texas Plaintiffs (the "*Aoki*" bellwether, No. 3:13-cv-1071-K). On July 15, 2016, the Court entered a Scheduling

Order providing that six cases involving California Plaintiffs Andrews, Davis, Metzler, Rodriguez, Standerfer, and Weiser be set for a third bellwether trial. They assert claims for negligence, strict liability, fraud, negligent misrepresentation, fraudulent business acts and practices, breach of express and implied warranty, and loss of consortium. Defendants' Motions seek to dismiss certain causes of action alleged by Plaintiffs.

II. Burden of Proof

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). The 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

Johnson & Johnson's Motion for Summary Judgment

In addition to each of the other motions for summary judgment addressed in this Order, Johnson & Johnson, Johnson & Johnson Services, Inc., Johnson & Johnson International, and DePuy Synthes, Inc. (the "Johnson & Johnson Defendants") filed a separate motion addressing the Johnson & Johnson Defendants' status as parties, rather than the merits of any cause of action (the "Johnson &

Johnson Motion"). The Johnson & Johnson Motion seeks summary judgment on Plaintiffs' product liability claims (including negligence, strict liability, and breach of express and implied warranties) and Plaintiffs' fraud-based claims (negligent misrepresentation, intentional misrepresentation, fraudulent concealment, and violation of the California Business and Professions Code).

A. Plaintiffs' Product Liability Claims

The Johnson & Johnson Defendants first contend that they are not sellers or manufacturers under California law and accordingly cannot be held liable on Plaintiffs' product liability claims arising out of the sale and manufacture of the Pinnacle Device. Rather, the Johnson & Johnson Defendants all are holding/parent companies or service providers: 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 second-level 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.

Plaintiffs respond that under California law, the Johnson & Johnson Defendants can be held strictly liable for Plaintiffs' product liability claims, as they are integral participants in the overall producing and marketing enterprise of the product. Furthermore, Plaintiffs contend that the Johnson & Johnson Defendants are liable for their own negligence and breaches of warranty.

1. Plaintiffs' Strict Liability Claims

Under California law, strict liability extends to all those who are "an 'integral part of the overall producing and marketing enterprise' . . . ." *O'Neil v. Crane Co.,* 266 P.3d 987, 995 (Cal. 2012). This liability applies to non-manufacturing parties playing an integral role in the production and marketing of a product and who profit from the product. *Arriaga v. CitiCapital Com. Corp.*, 85 Cal. Rptr. 3d 143, 149 (Cal. App. 5th Dist. 2008). For Defendants to be held "strictly liable under a marketing/distribution theory, [Plaintiffs] must demonstrate that: '(1) [Defendants] received a direct financial benefit from its activities and from the sale of the product; (2) [Defendants'] role was integral to the business enterprise such that [Defendants'] conduct was a necessary factor in bringing the product to the initial consumer market; and (3) [Defendants] had control over, or a substantial ability to influence, the manufacturing or distribution process.'" *Id.* at 149–50.

Taking the summary judgment evidence in the light most favorable to the Plaintiffs, fact issues exist precluding summary judgment on each of these elements. Plaintiffs' summary judgment evidence suggests the Johnson & Johnson Defendants benefitted financially from the sale of the Pinnacle Device, "cleared" DePuy's manufacture and sale of the Pinnacle Device, approved of DePuy's sales materials, oversaw DePuy's advertising campaign, permitted DePuy to use the "Johnson & Johnson" logo, and sponsored a nationwide telecast and website for the purpose of promoting Pinnacle devices.

As the Johnson & Johnson Defendants note, the Court previously considered this issue in both the *Paoli* and *Aoki* bellwether trials and denied the Johnson & Johnson Defendants' prior motions for summary judgment [*Paoli* (3:11-cv-03590-K) Doc. 99; *Aoki* (3:13-cv-01071) Doc. 90]. The Johnson & Johnson Defendants urge this Court to revisit the prior rulings but provide no new authority suggesting that these fact issues should be disregarded.

2. Plaintiffs' Negligence and Breach of Warranty Claims

Plaintiffs also contend that the Johnson & Johnson Defendants owe Plaintiffs a duty of care and as a result can be held liable for their own negligence. Such a duty can exist under California law when an entity voluntarily assumes a business relationship by its endorsement, "having in effect loaned its reputation to promote and induce the sale of a given product . . . ." *Hanberry v. Hearst Corp.*, 81 Cal. Rptr. 519, 522 (Cal. Ct. App. 4th Dist. 1969). The Restatement (Second) of Torts, adopted by the Supreme Court of California, also provides liability for physical harm caused by any direct or indirect supplier of a product, whether or not they also manufactured the product. Restatement (Second) of Torts § 388 & cmt. c (1965).

Plaintiffs have raised genuine issues of material fact concerning the Johnson & Johnson Defendants' conduct—*e.g.*, the clearance and approval for sale, oversight of advertising, and use of the Johnson & Johnson logo on the Pinnacle Device—which a reasonable jury could find to support a duty of care owed to the Plaintiffs under California law. The same factual allegations also preclude summary judgment on the

Johnson & Johnson Defendants' breach of warranty claims, as, taken in the light most favorable to Plaintiffs, this conduct could support a finding that the Johnson & Johnson Defendants were "sellers" of the Pinnacle Device.

The Johnson & Johnson Defendants' Motion for Summary Judgment is DENIED as to Plaintiffs' product liability claims.

B. Plaintiffs' Fraud-Based Claims

The Johnson & Johnson Defendants next contend that Plaintiffs' fraud-based claims fail because Plaintiffs have not identified any misrepresentation made by the Johnson & Johnson Defendants upon which Plaintiffs relied, necessary to Plaintiffs' claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and fraudulent business acts and practices. 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 by Johnson & Johnson's procured "thought leaders" at the Johnson & Johnson organized and sponsored satellite broadcast to over 1,500 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.

The Johnson & Johnson Defendants contend that these statements, alleged to be sponsored and approved by the Johnson & Johnson Defendants, are insufficient; however, "the rule generally is that one who accepts the fruits of a fraud, with knowledge of the misrepresentations or concealments by which the fraud was perpetrated, thereby inferentially ratifies the fraud complained of and will be liable therefor, even though he did not personally participate in the fraud, and this is so apart from any consideration of the theory of agency." *See McClung v. Watt*, 211 P. 17, 20 (Cal. 1922); *see also Engle v. Farrell*, 171 P.2d 588, 590–91 (Cal. Ct. App. 2d Dist. 1946) ("One who persuades his representative to commit a fraud, or who connives at a fraud, and knowingly takes the fruits thereof, is no less guilty than is his representative. And an agent who knowingly participates in a fraudulent transaction is equally responsible with his principal. Similarly, one who is not present at the time of the making of false representations but who profits by the fruits of the fraud, having sufficient knowledge of the facts to put a prudent person on inquiry, cannot evade responsibility.") (citation and internal quotation marks omitted).

Finally, Plaintiffs point to testimony of their implanting physicians indicating that these physicians received the Johnson & Johnson Defendants' representations and that their decisions to use the Pinnacle Device were not based exclusively on factors other than these alleged misrepresentations. Taking the facts in a light most favorable to Plaintiffs, this evidence raises a fact issue as to reliance on Defendants' statements when they chose to use the Pinnacle Device implants for Plaintiffs.

The Johnson & Johnson Defendants' Motion for Summary Judgment is DENIED as to Plaintiffs' fraud-based claims.

Design Defect Claims

Defendants' Motion for Partial Summary Judgment as to Plaintiffs' Design Defect Claims (the "Design Defect Motion") seeks to dismiss Plaintiffs' design defect claims (1) under comment k to Section 402A of the Restatement (Second) of Torts; (2) as based on an inherent feature of all metal-on-metal devices, rather than a specific design flaw; and (3) because such claims are purportedly preempted by federal law.

A. The Strict Liability Design Defect Bar

In the Design Defect Motion, Defendants first re-assert the argument that Plaintiffs have failed to state a claim upon which relief can be granted, as Section 402A, comment k, of the Restatement (Second) of Torts purportedly bars a strict liability design defect action in this matter. Defendants advanced this argument in their Partial Motion to Dismiss Plaintiffs' First Amended Complaints in this bellwether, which this Court denied. *See* Order Granting in Part and Denying in Part Defendants' Partial Motion to Dismiss Plaintiffs' First Amended Complaints in this Bellwether [*Andrews* (3:15-cv-3484) Doc. 82]. For the reasons set forth in that Order, Defendants' Design Defect Motion is DENIED as to the contention that Plaintiffs' strict liability design defect claims fail under comment k.

B. The Inherent Features of Metal-on-Metal Devices

Defendants next contend that Plaintiffs' design defect claims should be dismissed because Plaintiffs complain of an "inherent feature" of metal-on-metal devices rather than a design decision particular to the manufacturer's specific iteration of a product. In support of this argument, Defendants cite *Pooshs v. Philip Morris USA, Inc.*, 904 F. Supp. 2d 1009 (N.D. Cal. 2012). There, the court granted summary judgment on the purported "design defect" of a cigarette containing nicotine. *Pooshs*, 904 F. Supp. 2d. at 1025. As that court observed, a cigarette will by design contain tobacco, and "nicotine is normally present in tobacco." *Id.* By faulting the presence of nicotine in cigarettes, the plaintiffs in *Pooshs* did not attack the design of a particular type of cigarette, rather cigarettes as a whole. The same analysis does not apply to hip implants as a whole and Plaintiffs' complaints in this matter.

Plaintiffs have presented evidence that, while implanting an artificial hip into the body carries with it some risk, different designs of hip implants may increase or decrease that risk. Plaintiffs complain of purported hazards specific to the metal-on-metal devices, as compared to implants using metal-on–poly or ceramic-on-poly articulation, and *Pooshs* is inapposite. Moreover, even an "inherent feature" of a product would not preclude a products liability action sounding in negligent design. *See Brown v. Superior Court*, 751 P.2d 470, 483 n.12 (Cal. 1988); *Garrett v. Howmedica*

Osteonics Corp., 153 Cal. Rptr. 3d 693, 700 (Cal. Ct. App. 2013); *Scott v. C.R. Bard, Inc.*, 180 Cal. Rptr. 3d 479, 489 (Cal. Ct. App. 2014).

Defendants' Design Defect Motion is DENIED as to the contention that Plaintiffs' design defect claims fail as challenging an "inherent feature" of the Pinnacle Device.

C. Federal Preemption

Finally, Defendants' Design Defect Motion seeks to dismiss Plaintiffs' design defect claims as preempted under federal law. Defendants contend that these 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. Defendants allege that it is impossible to independently comply with both state and federal requirements, and as such, Plaintiffs' state law design defect claims are preempted under *Mensing*. The *Mensing* matter, however, involved the preemption of failure-to-warn claims for generic prescription drugs which required FDA evaluation on the drugs and accompanying warnings prior to marketing.

As this Court observed in the *Aoki* bellwether, the FDA evaluation process for prescription drugs differs from the process applicable to the Pinnacle Device. 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). In *Medtronic v. Lohr*, 518 U.S. 470 (1996), the Supreme Court held that the 510(k) clearance process, by which the Pinnacle Device was approved, does not preempt state-law design defect claims. 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. Defendants, therefore, could not have been subject to conflicting state and federal design requirements that would give rise to preemption.

Defendants also attempt to argue that Plaintiffs' design defect claims are "impliedly preempted" as the 510(k) clearance process prohibits a manufacturer's unilateral change after approval. However, this product restriction is not equivalent to impossibility; it is neither a "duty of sameness" for generic drugs that prohibits changes or a coexisting "state-law duty to change the label and . . . federal law duty to keep the label the same." *Mensing*, 131 S. Ct. at 2578. Rather, *Lohr* controls; "[t]he FDA's 'substantially equivalent' determination as well as its continuing authority to exclude a device from the market do not amount to a specific, federally enforceable design requirement" running in conflict with state liability law. *Lohr*, 518 U.S. at 471. With the 510(k) process, manufacturers enjoy the benefit of being able to "rapidly introduce [devices] into the market," but that benefit comes at the cost of "hav[ing] to defend itself against state-law claims" when those devices cause harm.

Id., at 478, 494. The 510(k) process does not give rise to express or implied preemption.

Defendants' Design Defect Motion is DENIED as to the contention that Plaintiff's claims are preempted under federal law.

Premarket Approval/Metal-on-Metal Defect Claims

Defendants' Motion for Partial 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 (the "Premarket Approval Motion") seeks summary judgment on all claims to the extent that 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.

Defendants contend that these claims are preempted by federal law. First, Defendants contend 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 Defendants should have used the alternate, more rigorous clearance process interferes with the FDA's authority. Second, Defendants also contend 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.

As discussed above, product manufacturers may seek FDA approval through either the PMA or 510(k) process. Both Plaintiffs and Defendants acknowledge that both procedures are lawful mechanisms for obtaining FDA approval. Accordingly, Defendants argue that any state law imposing liability on Defendants for using the 510(k) process rather than the more rigorous PMA process are preempted, as they interfere with the FDA's authority to determine its own clearance procedures. However, 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 510(k) process are not.

While DePuy had the right to proceed under the 510(k) process—and Plaintiffs do not assert that Defendants are per se liable because of that election—nothing in the law permits that process to be used as a shield against inquiry regarding the approval process. Defendants argue that imposing liability for a device approved under the 510(k) process would discourage manufacturers from using the process, cause more device manufacturers to elect the slower and more onerous PMA process, and defeat the 510(k) purpose of rapid product availability to consumers. However, it is the manufacturer's benefit to "rapidly introduce [devices] into the market" under the 510(k) process which bears with it the cost of "hav[ing] to defend itself against state-law claims" when those devices cause harm. *Lohr*, 518 U.S. at 494.

Defendants also contend 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 premarket approval are preempted. *Riegel v. Medtronic, Inc.*, 522 U.S. 312 (2008). However, this preemption applies specifically to items cleared through the rigorous PMA process, rather than the alternative 510(k) "grandfathering" practice. 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' Premarket Approval Motion is DENIED.

Failure to Warn/Fraud

Defendants' Motion for Summary Judgment on Claims Sounding in Failure to Warn and Fraud (the "Failure to Warn Motion") seeks summary judgment on Plaintiffs' claims for failure to warn, fraud, and fraudulent business acts and practices in violation of the California Unfair Competition Law ("UCL"), as Defendants contend that Plaintiffs cannot prove a causal connection between Defendants' representations and the alleged injuries. In other words, Defendants contend

Plaintiffs cannot meet their burden to demonstrate that their surgeons relied upon Defendants' statements in using the Pinnacle Device, or that a different representation or warning would have prevented their surgeons from using the Pinnacle Device.

Under California law, a plaintiff asserting a claim sounding in failure to warn must ultimately demonstrate that the absence of a warning or inadequate warning was a "substantial factor" in bringing about the plaintiff's injury. *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd sub nom.*, 358 F.3d 659 (9th Cir. 2004) (citing *Rutherford v. Owens-Ill., Inc.*, 941 P.2d 1203 (Cal. 1997)). "The substantial factor standard is a relatively broad one, requiring only that the contribution of the individual cause be more than negligible or theoretical." *Rutherford*, 941 P.2d at 1220. Where a plaintiff can show that a stronger warning would have altered the plaintiff's conduct, the warning provided will be considered both inadequate and a substantial factor in bringing about the plaintiff's injury. *See Georges v. Novartis Pharms. Corp.*, 988 F. Supp. 2d 1152, 1157 (C.D. Cal. 2013) (citing *Motus*, 196 F. Supp. 2d at 991).

Similarly, a plaintiff alleging common law fraud, statutory fraud, or negligent misrepresentation under California law must prove causation, or that the party acted in reliance upon the representation at issue. *See In re Tobacco II Cases*, 207 P.3d 20, 26 (Cal. 2009) (a plaintiff "proceeding on a claim of misrepresentation as the basis of his or her UCL action must demonstrate actual reliance on the allegedly deceptive or

misleading statements, in accordance with well-settled principles regarding the element of reliance in ordinary fraud actions"). Under the learned intermediary doctrine, applicable in California, a manufacturer's duty to warn of alleged risks runs to the treating physician, not the patient. *Motus*, 196 F. Supp. 2d at 990. Thus, a patient alleging failure to warn must present evidence that a different warning would have changed their physician's decision to take a particular course of action. *Id.*at 995.

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 advertisements and instead conducted their own research. DePuy argues, therefore, that Plaintiffs cannot prove causation or reliance in its claims sounding in failure to warn and fraud.

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

1. Dr. Rose is the implanting physician for Plaintiff Davis. Dr. Rose attends meetings of the American Academy of Orthopedic Surgeons ("AAOS"). DePuy attends AAOS meetings, and at the 2007 AAOS conference DePuy presented a poster falsely touting a 99.9% five-year survival rate for the Pinnacle Device.
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 attended by all of Plaintiffs' implanting physicians.
3. Dr. Howe, the implanting physician for Plaintiff Standerfer, testified his opinion was biased in favor of using the Pinnacle Device after seeing an advertisement touting the Pinnacle Device's 99.9% five-year survival rate.

4. Dr. Howe testified that he probably read the surgical technique brochure for the Pinnacle Device, provided by DePuy and that one of DePuy's sales representatives taught him how the hip worked and how to implant the device into patients.

5. Dr. Huddleston, the implanting physician for Plaintiff Weiser, reviewed and relied upon information provided by Defendants' sale representatives, such as the fact that there would be no metal wear debris and that the Pinnacle Device was a lifetime hip in making clinical decisions for his patients.

6. Dr. Miric, the implanting surgeon for Plaintiff Rodriguez, testified that he expected information provided to him by Defendants' sale representatives to be truthful because he believed the manufacturer to know the most about the product's risks and benefits.

7. Dr. Miric testified that he read and relied upon warning manuals and technical monographs to obtain information used in making the decision to implant his patients with the Pinnacle Device.

8. Dr. Woods, the implanting physician for Plaintiff Metzler, testified that Defendants' sale representatives indicated that the Pinnacle Device would potentially last for a patient's lifetime, which he considered when deciding to implant Ms. Metzler with the Pinnacle Device.

9. Dr. Tay, the implanting physician for Plaintiff Andrews, testified that although he could not recall whether he relied upon Defendants' representations, were he provided with specific information about the metal-on-metal hip, it would be consistent with his practice to consider that information in coming to a decision as to whether to implant the Pinnacle Device.

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

11. Plaintiffs Andrews, Davis, Metzler, Rodriguez, Standerfer, and Weiser would not have consented to the implantation of the Ultamet device if they had been warned about its true risks.

Considering all this evidence, the Court finds that a fact issue exists as to whether Plaintiffs' implanting surgeons relied upon Defendants' misrepresentations and omissions concerning the Pinnacle Device and would have acted differently had Defendants been transparent about the true risks of the Pinnacle Device.

Defendants' Failure to Warn Motion is DENIED.

Warranty Claims

Defendants' Motion for Partial Summary Judgment as to Plaintiffs' Warranty Claims (the "Warranty Motion") seeks summary judgment on Plaintiffs' claims for breach of express warranty, breach of the implied warranty of fitness for a particular purpose, and breach of the implied warranty of merchantability based on privity of contract between Plaintiffs and Defendants. Defendants also seek summary judgment on Plaintiffs' claim for breach of the implied warranty of merchantability, as Defendants contend there is no evidence that any of the Plaintiffs or their physicians selected the Pinnacle Device for a special or particular purpose separate and apart from its ordinary purpose as a hip implant.

A. Privity of Contract

A claim for a breach of express or implied warranty under California law requires contractual privity between the parties. *See Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1023 (9th Cir. 2008) (citing *Anunziato v. eMachines, Inc.*, 402 F. Supp. 2d 1133, 1141 (C.D. Cal. 2005); *see also Tapia v. Davol, Inc.*, 116 F. Supp. 3d 1149, 1159 (S.D. Cal. 2015). "A buyer and seller stand in privity if they are in adjoining links of the distribution chain." *Clemens*, 534 F.3d at 1023 (citing *Osborne v. Subaru of Am. Inc.*, 198 Cal. App. 3d 646, 656 n.6 (Cal. Ct. App. 1988)).

For express warranty claims, Defendants acknowledge that a plaintiff may satisfy the privity requirement where a "plaintiff's decision to purchase the product

was made in reliance on the manufacturer's written representations in labels or advertising materials." *Schwartz v. Wright Med. Tech., Inc.*, No. EDCV 14-01615 JGB (SPx), 2014 WL 11320637, at *4 (C.D. Cal. Sept. 11, 2014) (Bernal, J.) (quoting *Fieldstone Co. v. Briggs Plumbing Prods., Inc.*, 54 Cal. App. 4th 357 (Cal. Ct. App. 1997)). While a plaintiff need not directly receive the materials, the plaintiff must be exposed to the information contained in the materials in some manner. *See Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs., & Prods. Liab. Litig.*, 754 F. Supp. 2d 1145, 1183 (C.D. Cal 2010). For implied warranty claims, California courts have acknowledged a privity exception permitting a manufacturer's sale of a prescription drug to a distributor or retailer to form the basis of the ultimate patient's claim against the initial manufacturer. *See Wendell v. Johnson & Johnson*, No. C 09-04124 CW, 2010 WL 271423, at *5 (N.D. Cal. Jan. 20, 2010) (Wilken, J.) (citing *Gottsdanker v. Cutter Labs.*, 6 Cal. Rptr. 320 (Cal App. 2d 1960); *see also Carlin v. Superior Court*, 920 P.2d 1347, 1355 (Cal. App. 4th 1996)). Defendants argue that there is no evidence that any of Plaintiffs' implanting surgeons relied on any written or other representations by Defendants in selecting the Pinnacle Devices at issue.

However, the summary judgment evidence viewed in the light most favorable to Plaintiffs shows that Defendants marketed the Pinnacle Device as "uniquely designed to meet the demands of active patients;" each of Plaintiffs' prescribing physicians advised them that the Pinnacle Device was the best choice for Plaintiffs, and Plaintiffs' physicians reached their opinions about the efficacy of the Pinnacle

Device based at least in part on marketing and promotion by Defendants to hospitals and surgeons via written materials, the use of 'celebrity endorser' surgeons, 'seeding' studies in the medical literature, and through their network of sales representatives. Plaintiffs' physicians indicated a "bias" after seeing Defendants' advertisements, recalled studying Defendants' manuals, typically read promotional materials, or testified to relying at least somewhat on manufacturer representative statements. A fact issue accordingly exists as to reliance on Defendants' representations and the privity necessary for Plaintiffs' breach of warranty claims.

B. Selection for a "Particular Purpose"

Defendants next argue that Plaintiff's claims for breach of the implied warranty of fitness for a particular purpose fail because there is no evidence of a "special purpose" for which the Pinnacle Device was purchased or used. The California Commercial Code implies a warranty of fitness for a particular purpose "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select of furnish suitable goods . . . ." Cal. Com. Code § 2315. Defendants specifically contend that Plaintiffs have alleged—and can present evidence of—only an intent to use the Pinnacle Device for its "ordinary purpose," not the special purpose required by law.

As this Court has previously observed—in the *Paoli* bellwether, as well as Defendants' Motion to Dismiss under Rule 12(b)(6) in this matter—Plaintiffs have

alleged a particular or special purpose for their hip implants. Taking the summary judgment evidence in the light most favorable to Plaintiffs, Plaintiffs have set forth evidence presenting a fact issue for trial, that Defendants marketed the Pinnacle Device as especially suitable for younger and/or more active patients, unlike a typical hip replacement, and that each of the Plaintiffs, under the age of 70, are the type of young patient to whom Defendants marketed the Pinnacle Device.

Defendants' Warranty Motion is DENIED.

SO ORDERED.

Signed October 3rd, 2016.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE