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 GRANTING IN PART AND DENYING IN PART DEFENDANTS' PARTIAL MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINTS

Before the Court is Defendants' Partial Motion to Dismiss Plaintiffs' First Amended Complaints ("Defendants' Motion") [*Andrews*, 3:15-cv-03484-K, Doc. 21; *Davis*, 3:15-cv-01767-K, Doc. 25; *Metzler*, 3:12-cv-02066-K, Doc. 26; *Rodriguez*, 3:13-cv-03938-K, Doc. 20; *Standerfer*, 3:14-cv-01730-K, Doc. 23; and *Weiser*, 3:13-cv-03631-K, Doc. 24]. For the reasons set forth herein, Defendants' Motion is GRANTED IN PART AND DENIED IN PART.

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 DePuy's 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. The MDL has now been pending over five years.

In September and October 2014, the Court held the first bellwether trial, involving a Montana Plaintiff and her husband (the "*Paoli*" bellwether, No. 3:12-cv-04975-K). The Court held a second bellwether trial in January through March 2016, consolidating five cases brought by Texas Plaintiffs [*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 (collectively, the "*Aoki*" bellwether)].

On July 15, 2016, the Court entered a Scheduling Order providing that six California cases, identified above, be set for a third bellwether trial beginning September 26, 2016. Defendants' Motion seeks to dismiss under Federal Rule of Civil Procedure 12(b)(6) certain claims alleged by Plaintiffs in the third bellwether trial, specifically for (1) strict liability design defect; (2) strict liability manufacturing defect; (3) fraudulent business acts and practices; (4) negligence per se; and (5) breach of the implied warranty of fitness for a particular purpose. Having considered

the briefing of both parties, the Court addresses each of Defendants' grounds for dismissal in turn.

LEGAL STANDARD

The Federal Rules of Civil Procedure require a plaintiff to plead "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Such a pleading must give "the defendant notice of what the . . . claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957). Plaintiffs must provide the grounds of their entitlement to relief, which "requires more than labels and conclusions." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 564 (2007). "[A] formulaic recitation of the elements of a cause of action will not do." *Id.* "*Twombly* . . . requires that a complaint allege enough facts to state a claim that is plausible on its face." *St. Germain v. Howard,* 556 F.3d 261, 263 n. 2 (5th Cir.2009) (citing *In re Katrina Canal Breaches Litig.*, 495 F.3d 191, 205 (5th Cir.2007)). Furthermore, for causes of action alleging fraud, the complaint must "state with particularity" the circumstances alleged to constitute such fraud. Fed. R. Civ. P. 9(b). In other words, the plaintiff must plead the "time, place, and contents of the false representations as well as the identity of the person making the misrepresentation, and what [that person] obtained thereby." *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 177 (5th Cir.) (quoting *Tuchman v. DSC Comms. Corp.*, 14 F.3d 1061, 1068 (5th Cir. 1994)).

A court reviewing a motion to dismiss for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) must construe the complaint in favor of the plaintiff and take all well-pleaded facts as true. *Kane Enterprises v. MacGregor (USA), Inc.*, 322 F.3d 371, 374 (5th Cir. 2010). Rule 12(b)(6) also allows dismissal when "a defendant attacks the complaint because it fails to state a legally cognizable claim." *Ed & F Man Biofuels Ltd. v. MV FASE*, 728 F. Supp. 2d 862, 866 (S.D. Tex. 2010) (quoting *Ramming v. United States,* 281 F.3d 158, 161 (5th Cir. 2001), *cert. denied sub nom. Cloud v. United States,* 536 U.S. 960 (2002)). A federal court sitting in diversity applies the substantive law of the state of proper jurisdiction. *See Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 417 (2010) (Stevens, J., concurring). All Parties acknowledge that the substantive law of California applies to Plaintiffs' claims at issue.

ANALYSIS

A. Plaintiffs Sufficiently State a Claim for Strict Liability Design Defect.

Defendants first contend that California law does not recognize a cause of action for strict liability arising out of a design defect for medical devices. As the Fifth Circuit has observed, "to determine issues of state law, we look to final decisions of the state's highest court, and when there is no ruling by that court, then we have the duty to determine as best we can what the state's highest court would decide." *James v. State Farm Mut. Auto. Ins. Co.*, 743 F.3d 65, 69 (5th Cir. 2014) (citing *Westlake Petrochems., LLC v. United Polychem, Inc.*, 688 F.3d 232, 238 n.5 (5th Cir.

2012)). In such a circumstance, the Court makes a so-called "*Erie* guess" concerning the substantive state law to be applied. *Gulf & Miss. River Transp. Co. v. BP Oil Pipeline Co.*, 730 F.3d 484, 488 (5th Cir. 2013); *see also Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938).

California has adopted comment k of section 402A of the Restatement (Second) of Torts concerning "unavoidably unsafe" items which, while "useful and desirable" also contain "a known but apparently reasonable risk," and has specifically held that manufacturers of prescription drugs cannot be held strictly liable for injuries caused by those prescription items so long as adequate warnings were provided. *Brown v. Superior Court*, 44 Cal. 3d 1049, 1069 (Cal. 1988) (citing Restatement (Second) of Torts § 402A cmt. k (1965)). The Supreme Court of California has not specifically ruled on the issue of whether such a strict liability shield applies to medical devices, such as the Pinnacle devices at issue in Plaintiffs' claim. The rationales and analyses underlying the *Brown* decision, however, suggest that the Supreme Court of California's holding would not preclude Plaintiffs' instant claim.

The FDA approval process for medical devices requires either premarket approval following reasonable assurance to the FDA of a device's safety and effectiveness or, alternatively, if a device is substantially equivalent to a pre-existing device, a premarket notification to the FDA, known as a §510(k) notification and clearance. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The §510(k) mechanism permits a device to be marketed without further regulatory analysis. *See*

id. The Pinnacle Device was approved pursuant to §510(k) and its substantial equivalence to an existing device.

In addressing the liability of manufacturers of prescription drugs, the *Brown* decision reasons that a strict liability shield for design defect was appropriate, as withholding prescription drugs *until a safer alternative was available* would not serve the public interest. *Id.* at 1062-63 (emphasis added). Under this reasoning, manufactured devices such as the Pinnacle Device—which were approved based on the very existence of an alternative available device—are easily distinguished. Because there is necessarily an alternative device, the Supreme Court of California's analysis in *Brown* cannot be said to provide a strict liability shield for devices approved pursuant to §510(k).

Defendants point to several decisions from California's intermediate appellate courts, but these decisions are not controlling "where the highest court of the State has not spoken on the point." *Ergon-W. Va., Inc. v. Dynergy Mktg. & Trade*, 706 F.3d 419, 426 n.6 (5th Cir. 2013) (emphasis added), *quoting C.I.R. v. Bosch's Estate*, 387 U.S. 456, 465 (1967).

Defendants' Motion is DENIED as to Plaintiffs' strict liability design defect claims.

B. Plaintiffs Have Withdrawn Their Claims for Strict Liability Manufacturing Defect.

Defendants' Motion contends that Plaintiffs have failed to state a claim for strict liability manufacturing defect because they do not allege that any one Pinnacle

device was defective (*i.e.*, that a Plaintiff's device was manufactured differently than other Pinnacle devices or deviated from product specifications). Since the time of Defendants' initial briefing, counsel for Plaintiffs have confirmed to the Court that they will no longer pursue a strict liability manufacturing defect claim for Plaintiffs Andrews, Davis, Metzler, Rodriguez, Standerfer, and Weiser.

Defendants' Motion is DENIED as moot as to Plaintiffs' strict liability manufacturing defect claims.

C. Plaintiffs Sufficiently State a Claim for Fraudulent Business Acts and Practices.

Defendants assert that Plaintiffs' claim for fraudulent business acts and practices under the California Unfair Competition Law ("UCL") first fails because Plaintiffs have not sufficiently pled reliance and second fails to the extent Plaintiffs have requested damages unavailable under the UCL. Specifically, Defendants argue that Plaintiffs' live complaints are "devoid of any allegations capable of supporting the inference that either their doctors or they themselves relied on defendants' supposedly fraudulent conduct and, thus, their barebones allegations 'cannot satisfy . . . Rule 12(b)(6) or Rule 9(b).'" Defendants' Brief at 9 (citing *In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2009 U.S. Dist. LEXIS 103408, at *34 (N.D. Cal. Nov. 6, 2009), *aff'd*, 464 F. App'x 651 (9th Cir. 2011)). Reliance is established by showing that, but for the defendant's fraudulent conduct, the plaintiff would not have engaged in the "injury-producing conduct." *In re Tobacco II Cases*, 207 P.3d 20,

39 (Cal. 2009) (citing *Mirkin v. Wasserman*, 858 P.2d 568 (Cal. 1993) (Kennard, J., concurring in part & dissenting in part)). A plaintiff asserting a violation of the UCL must also show that she has "suffered injury in fact and has lost money or property as a result of the unfair competition." Cal. Bus. & Prof. Code § 17204.

Plaintiffs' Complaints allege that Defendants marketed the Pinnacle Device as a safe and superior device despite concealed risks, that "99.9% of Pinnacle hip components are still in use today," and that Plaintiffs and/or their doctors relied on misrepresentations of material facts regarding the safety, effectiveness, and fitness of the Pinnacle Device. Plaintiffs further assert that "[h]ad Defendants not concealed the known defects, the early failure rate, the known complications, and the unreasonable risks associated with the use of the Pinnacle [ ] Device, [Plaintiffs] would not have consented to the Pinnacle [ ] Device being [implanted]." Liberally construed, Plaintiffs' Complaints sufficiently plead reliance upon Defendants' allegedly fraudulent business practices in compliance with Rule 9(b).

Additionally, Plaintiffs assert that they "suffered injury in fact and [ ] lost money or property as a result of Defendants' conduct." Pursuant to Section 17204 of the California Business and Professions Code, Plaintiffs may recover damages in restitution for a violation of the UCL. *See In re Actimmune*, 2009 WL 3740648 at *8. Because Plaintiffs seek the "money or property, real or personal, which may have been acquired by means of such unfair competition," which is recoverable here, *see*

Cal. Bus. & Prof. Code § 17203, this is not a basis to dismiss Plaintiffs' claim for fraudulent business acts and practices.

Defendants' Motion is DENIED as to Plaintiffs' claims for fraudulent business acts and practices.

D. Plaintiffs Fail to Sufficiently State a Claim for Negligence under the Theory of Negligence Per Se.

Defendants next contend that Plaintiffs' claims for negligence per se, based in a purported violation of the UCL, should be dismissed as (1) negligence per se is not an independent cause of action under California law, and (2) the UCL does not establish a duty of care applicable to a negligence cause of action. Plaintiffs acknowledge the absence of such a specific cause of action but argue that California courts routinely recognize and apply the evidentiary presumption of negligence per se when properly invoked under a negligence cause of action. In other words, Plaintiffs argue that dismissal is improper "merely because Plaintiffs have broken out and separately stated their claim for negligence based on the presumption of negligence per se." Because the evidentiary presumption of negligence per se is available under California law if all other requirements are met, Plaintiffs' notice to all parties that it intends to seek such a presumption does not serve as a basis to dismiss.

Under California law, the negligence per se evidentiary presumption applies when a plaintiff alleges that "(1) the defendant violated a statute, ordinance, or regulation; (2) the violation proximately caused injury; (3) the injury resulted from an occurrence that the enactment was designed to prevent; and (4) the plaintiff fits

within the class of persons for whose protection the enactment was adopted." *Coppola v. Smith*, 935 F. Supp. 2d 993, 1016–17 (E.D. Cal. 2013) (citing Cal. Evid. Code § 669; *Ramirez v. Nelson,* 44 Cal.4th 908, 80 Cal.Rptr.3d 728 (Cal. 2008); *Newhall Land and Farming Co. v. Superior Court,* 19 Cal.App.4th 334, 347 (Cal. 1993)). The violation of a statute itself, however, does not entitle a plaintiff to recover damages; the plaintiff is merely relying upon a violation of the statute to establish part of a negligence cause of action. *Sierra-Bay Fed. Land Bank Ass'n v. Superior Court*, 227 Cal. App.3d 318, 333-34 (Cal. Ct. App. 1991).

As a result, when the violation of a statute does not amount to negligence—and is instead more properly "treated as trespass, conversion, fraud, nuisance, libel or slander, malicious prosecution or perhaps any other tort," the statutory violation is not properly the basis for a negligence per se presumption. *See Cal. Serv. Station & Auto. Repair Ass'n v. Am. Home Assurance Co.*, 62 Cal. App. 4th 1166, 1179 (Cal. Ct. App. 1998) (citing Prosser, *Contributory Negligence as Defense to Violation of Statute*, 32 Minn. L. Rev. 105, 109-110 (1948)). Plaintiffs' allegations concerning the UCL concern consumer fraud and do not sound in negligence; these claims cannot properly form the basis for a negligence per se presumption under California law.

Defendants' Motion is GRANTED as to Plaintiffs' claims for negligence per se.

E. Plaintiffs Sufficiently State a Claim for Breach of Implied Warranty of Fitness for a Particular Purpose.

Finally, Defendants argue that Plaintiffs have failed to identify a particular or special purpose for which their hip implants were intended to be used outside of the

general purpose of serving as a "safe and effective hip replacement." Plaintiffs counter that, as each of the Plaintiffs were under 70 at the time their Pinnacle Devices were implanted, they are the sort of young and active patient for whom this Court found a particular purpose in the first bellwether trial. Alternatively, Plaintiffs contend that the "general purpose" of these specialized devices is in fact a "particular or special purpose." However, Plaintiffs also explicitly assert that Defendants' marketed the Pinnacle Device as "especially suitable for younger and/or more active patients," and that "Plaintiff[s] . . . were relying on [Defendants'] skill, judgment, and reputation . . . ." *See, e.g.*, Andrews Amended Complaint [Doc. 12] at 13, 36. 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. Plaintiffs have therefore sufficiently pled a claim for breach of implied warranty of fitness for a particular purpose so as to give Defendants notice of what is claimed and the grounds upon which the claim rests.

Defendants' Motion is DENIED as to Plaintiffs' claims of breach of implied warranty of fitness for a particular purpose.

SO ORDERED.

Signed September 20th, 2016.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE