UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

ROGER MILLER, an individual, Plaintiff, v. DePUY SPINE, INC., a Massachusetts corporation; JOHNSON & JOHNSON, INC., a New Jersey corporation; JDA SURGICAL ASSOCIATES, Inc., a California Corporation; DOES I-X; and ROE CORPORATIONS I-X, inclusive, Defendants.	Case No: 2:07-cv-01639-RJC-PAL **ORDER GRANTING MOTIONS FOR SUMMARY JUDGMENT OF DEPUY SPINE, INC. AND JDA SURGICAL ASSOCIATES, INC.**

Before the Court are defendant DePuy Spine, Inc.'s ("DePuy Spine") Motion for Summary Judgment (#52) and defendant JDA Surgical Associates, Inc.'s ("JDA") Motion for Summary Judgment (#63). After the time for plaintiff Roger Miller's response to the motions was enlarged to enable him to conduct discovery relating to the motions (##57, 66), Mr. Miller opposed both motions (##69, 70). DePuy Spine and JDA then filed reply briefs (##71, 72).

The Court heard oral arguments on April 6, 2009. Darwin Rygg appeared on behalf of Plaintiff Roger Miller. Robert McCoy and Michael Conner, appearing *pro hac vice*, appeared on behalf of defendants DePuy Spine and JDA.

The Court has considered the Motions, the briefs and submissions, and the parties' oral arguments. For the following reasons, the Court grants both motions.

Background

Mr. Miller underwent surgery on November 2, 2005, due to pain from a bulging disc between his L5 and S1 vertebrae. In that surgery, Dr. William Smith removed Mr. Miller's natural disc at that level and implanted a Charité Artificial Disc sold by defendant DePuy Spine. Mr. Miller alleges that after implantation of the Charité Disc, he has continued to have back pain and that he has had additional surgery to fuse his L4 and L5 vertebrae. The Charité Disc has not been removed and remains implanted.

Mr. Miller filed suit against DePuy Spine in the District Court of Clark County, Nevada, on November 1, 2007.[1] DePuy properly removed the case to this Court based on diversity of citizenship. JDA was joined as a defendant in Mr. Miller's First Amended Complaint, filed April 7, 2008. The First Amended Complaint alleges that the Charité Disc implanted in his spine was defective and seeks to impose liability on DePuy Spine and JDA under theories of strict product liability, negligence, and breach of implied and express warranties.

The motions argue that Mr. Miller's claims are barred by preemption under the Medical Device Amendments of the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §360k, as interpreted in *Riegel v. Medtronic, Inc.*, 552 U.S. ___, 128 S. Ct. 999 (2008), because the Charité Disc received Pre-Market Approval (PMA) from the U.S. Food and Drug Administration (FDA).[2]

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[1] Mr. Miller's original complaint also asserted claims against DePuy Spine's corporate parent, Johnson & Johnson. Johnson & Johnson was dismissed on motion for lack of personal jurisdiction. (#30).

[2] JDA's motion additionally argues for summary judgment because JDA was not a seller of the Charité Disc or otherwise liable under Nevada law. The Court does not reach this argument because the preemption ground is dispositive.

Discussion

I. Standard of Review.

Summary judgment is appropriate if no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A fact is material if it might affect the outcome of the suit under the governing law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In support of its motion for summary judgment, the moving party need not negate the opponent's claim. *See Celotex*, 477 U.S. at 323. The moving party will be entitled to judgment if the evidence is not sufficient for a jury to return a verdict in favor of the opponent. *See Anderson*, 477 U.S. at 249.

When a properly supported motion for summary judgment has been presented, the adverse party "may not rely merely on allegations or denials in its own pleading." Fed. R. Civ. P. 56 (e). Rather, the non-moving party must set forth "specific facts" demonstrating the existence of a genuine issue for trial. *Id; Anderson*, 477 U.S. at 256. A party cannot create a genuine issue for trial by asserting "some metaphysical doubt" as to the material facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586. When the record, taken as a whole, could not lead a rational trier of fact to find for the nonmoving party, summary judgment is warranted. *See Miller v. Glenn Miller Prod., Inc.*, 454 F. 3d 975, 988 (9th Cir. 2006).

II. Preemption under 21 U.S.C. §360k and *Riegel v. Medtronic.*

Section 360k of the FDCA states in pertinent part:

> (a) General rule. … [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

In *Riegel*, the Supreme Court found that the grant of a PMA means that the device has been determined by the FDA to be safe and effective and creates federal requirements: "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 1007. Further, the Supreme Court held that state tort law standards which would require a device to be made or labeled differently from the PMA requirements were preempted under §360k: "State tort law that requires a manufacturer's [devices] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Id.* at 1008. Based on this analysis, the Supreme Court affirmed the district court's summary judgment ruling that the FDCA expressly preempted state law "claims of strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing and sale of the [device]." *Id.* at 1006.

III. Disposition of Plaintiff's Claims.

There is no dispute that on October 24, 2004, prior to Mr. Miller's surgery, the FDA granted a PMA to the Charité Disc. The record also establishes that the Charité Disc underwent the type of rigorous review by the FDA described in *Riegel* prior to its issuance of the PMA and its approval of the labeling to be used with the Charité Disc.

The *Riegel* decision is direct precedent for summary judgment in favor of DePuy Spine on Mr. Miller's claims based on strict product liability, negligence,

and implied warranty.[3] These claims are based on the hypothesis that the design and manufacture of, or warnings given with, the Charité Disc should have been different from what was approved by the FDA in granting its PMA to the Charité Disc. These claims can prevail only by imposing a state law requirement on the Charité Disc which is different from or in addition to the federal requirements imposed by the PMA and are therefore preempted under 21 U.S.C. §360k.

Mr. Miller's claim based on express warranty also fails on two grounds. First, Mr. Miller's discovery responses confirm that he never received any communications from DePuy Spine. Therefore he could not have received any "affirmation of fact or promise made by the seller to the buyer," a requirement for existence of an express warranty under Nev. Rev. Stat. §104.2313. There is no genuine issue as to this dispositive fact. Second, Mr. Miller's pleading allegations as to express and implied warranty deal with safety and effectiveness of the Charité Disc, subjects upon which the FDA made affirmative findings and approved labeling to accompany the product. Where, as here, an essential element of a plaintiff's claim of breach of express or implied warranty will be proof that a device granted a PMA is not safe or effective, such a contention necessarily conflicts with the FDA's contrary finding and its requirement that the device be made as approved. Such a warranty claim is directly preempted by *Riegel*. *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Lit.*, 592 F. Supp. 2d 1147, 1164 (D. Minn. 2009). Similarly, if a plaintiff's claim requires a finding that text or information in labeling approved by the FDA is false, *e.g.*, Mr. Miller's contention that a warranty was breached because he did not get "natural motion" from his Charité Disc, the claim is preempted because it would impose liability for the defendant's use of labeling approved and required by the FDA. *Gomez v.*

[3] Since *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, … to breach of warranty, … to failure to warn and manufacturing-and-design defect." *In re Medtronic Inc. Sprint Fidelis Leads Prod. Liab. Lit.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (collecting cases).

St. Jude Med. Diag. Div., 442 F. 3d 919, 932 (5th Cir. 2006;); *Parker v. Stryker Corp.*, 584 F. Supp. 1298, 1302-03 (D. Colo. 2008).

IV. Mr. Miller's Arguments to Avoid Judgment.

The Court rejects Mr. Miller's arguments to try to avoid summary judgment.[4]

Mr. Miller argues that 21 U.S.C. §360k preempts only claims based on state law requirements that are "different from or in addition to" federal requirements and that claims which are based on a state law remedy for violation of federal requirements are not preempted. The *Riegel* opinion said that such claims, described as state law claims based on "parallel" duties, might survive express preemption under §360k, 128 S. Ct. at 906, and this Court does not disagree. Mr. Miller, however, has not met his burden to show that there is a genuine issue of fact as to any such "parallel" claim.

Mr. Miller has offered no evidence to show that the Charité Disc implanted in him was manufactured out of conformity with the materials or manufacturing specifications approved by the FDA in the PMA granted for the Charité Disc. Only a departure from such FDA-approved specifications could conceivably escape preemption, and absence of any evidence of such departure justifies summary judgment. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 230-32 (6th Cir. 2000);

[4] The Court rejects Miller's contention that DePuy Spine is estopped from seeking summary judgment in this Court because a trial court in Massachusetts in 2007 denied a motion for summary judgment filed by DePuy Spine in some other cases arising from implantation of Charité Discs, before the Supreme Court explained the scope of PMA preemption in *Riegel*. The trial court's denial of summary judgment would not have issue preclusion effect under Massachusetts law, and therefore could not have such an effect in a federal court. 28 U.S.C. §1738; Mass. R. Civ. P. 54(a); *In re Strangie*, 192 F. 3d 192, 195 (1st Cir. 1998).

Rousseau v. DePuy Orthopaedics, Inc., 2006 WL 3716061 at *9-10 (W.D. La. Dec. 13, 2006).[5]

Mr. Miller has also asserted that DePuy Spine may have misrepresented or omitted material information in its submissions to FDA to secure or maintain the PMA. This contention fails to defeat summary judgment for several reasons.

First, Mr. Miller offers nothing but argument about this hypothesis, not any admissible evidence, so there is no genuine issue of material fact which could preclude summary judgment. *Orr v. Bank of America*, 285 F. 3d 764, 773 (9th Cir. 2002) ("A trial court can consider only admissible evidence in ruling on a motion for summary judgment.").

Second, Congress has stated its intent that the FDCA and regulations thereunder be enforced only by the U.S. Government. 21 U.S.C. §337(a). Because of this statement of legislative intent, Nevada law would not provide a damages remedy for any violation of FDA regulations, including those governing delivery of information to the FDA. *See Bell v. Alpha Tau Omega Fraternity*, 642 P.2d 161, 162 (Nev. 1982) (refusing to impose negligence *per se* for violation of a statute in absence of legislative intent to impose civil liability).

Finally, any claim by Mr. Miller based on a contention that DePuy Spine provided inaccurate or incomplete information to the FDA would be preempted due to the inherent interference of such allegations with the FDA's authority and its administration of federal law under the implied preemption principles stated in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

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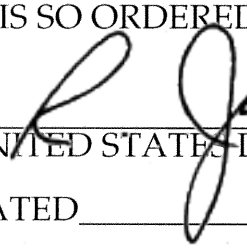
[5] In support of its motion, DePuy Spine submitted a declaration of a quality control engineer stating that Mr. Miller's Charité Disc components were manufactured in conformity with FDA-approved specifications. But even without DePuy Spine's affirmative proof, Mr. Miller's failure to produce evidence that his components were manufactured out of conformity with FDA-approved specifications is dispositive. Mr. Miller has the ultimate burden of proving a non-preempted manufacturing defect claim, and under Rule 56(e) and *Celotex*, he was required to provide sufficient evidence to support a verdict in his favor on that issue in order to defeat the pending motions.

Conclusion

This lawsuit has been pending for over 15 months. Mr. Miller had ample time to find and present evidence, if any exists, to counter defendants' Motions for Summary Judgment. Under Fed. R. Civ. P. 56(e), Mr. Miller was obligated to present admissible evidence to create a genuine issue of fact material to a claim which would survive preemption under 21 U.S.C. §360k. He has not done so. The Court finds that there is no genuine issue of material fact, and defendants are entitled to judgment as a matter of law.

For the foregoing reasons, IT IS HEREBY ORDERED that defendants' Motions for Summary Judgment are GRANTED and that judgment for defendants DePuy Spine and JDA be entered.

IT IS SO ORDERED:



UNITED STATES DISTRICT JUDGE

DATED _____

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