UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES -- GENERAL

Case No. **CV 06-7430-VBF(PLAx)** Dated: **September 17, 2008**

Title: Camille Carson -*v*- Depuy Spine, Inc., et al.

PRESENT: HONORABLE VALERIE BAKER FAIRBANK, U.S. DISTRICT JUDGE

Rita Sanchez None Present Courtroom Deputy Court Reporter

ATTORNEYS PRESENT FOR PLAINTIFFS: ATTORNEYS PRESENT FOR DEFENDANTS:

None Present None Present

PROCEEDINGS (IN CHAMBERS): COURT ORDER RULING ON SUBMITTED MATTER - RENEWED MOTION OF DEFENDANT DEPUY SPINE, INC. FOR SUMMARY JUDGMENT

I. Ruling

After considering the papers filed and counsel's oral arguments at the hearing on September 15, 2008, the Court **GRANTS** the Renewed Motion of Defendant Depuy Spine, Inc. for Summary Judgment pursuant to grounds set forth in the moving party's papers as indicated herein. The Court finds as follows:

1. There is no genuine issue that the spinal disk at issue was manufactured in accordance with the specifications which were a part of the Premarket Approval (PMA) issued by the FDA.

• The evidence is that damage to the device was caused either while implanted in Plaintiff due to movement of her vertebrae, or by the removal surgery itself. Plaintiff does not rebut this or offer other evidence.

2. There is no genuine issue that Depuy did not violate any FDA regulations governing promotion of a medical device for an off-label use.

• There is a lack of evidence that Plaintiff's surgeon relied on any promotion of off- label use by Defendant. There is no evidence that the off-label use of the device caused Plaintiff's injuries.

II. Background

Dr. Michael Kropf implanted two Charite artificial spinal discs in Plaintiff Carson in February 2005. Ms. Carson began to experience severe back pain, and Dr. Kropf removed one of the discs in November of that year. (The removed device was presumably discarded.) In February 2007, Ms. Carson filed a complaint against Defendant disc manufacturer for products liability based on negligence, breach of warranty, and strict liability.

By Order dated June 21, 2007, this Court granted Defendant partial summary judgment on the warranty and strict liability claims, on grounds that the Medical Device Amendments of 1976 preempted those claims. See 21 U.S.C. 360k(a). Those state claims potentially conflicted or added to requirements which the FDA imposed on the device through the premarket approval process. The Court denied Plaintiff's negligence claim except "insofar as she alleges that the Defendants failed to comply with federal device-specific regulations, such as through a manufacturing defect claim." June 21, 2007 Order, p. 10.

III. Request to Revisit the June 21 Order

As a preliminary matter, Plaintiff, in her Opposition, requests the Court revisit its June 21 ruling on the grounds that the United States Supreme Court's February 28, 2008 decision in *Riegel v. Medtronic, Inc*., 128 S. Ct. 999 (2008) "would allow a claim of strict liability based on a manufacturing defect." Opp. at 3. First, Plaintiff should have timely raised this request in a motion for reconsideration, not

in a summary judgment opposition more than six months after *Riegel* was decided. Second, the basis for Plaintiff's request is unclear and inadequately briefed.

IV. Manufacturing-Defect Claim

Plaintiff basically sets forth two grounds from which a jury could infer a manufacturing defect: (1) The accelerated wear of the device observed by Dr. Kropf during the removal surgery, and (2) The breakage of the device into pieces.

A. Accelerated wear

During the removal surgery, Dr. Kropf observed that the disc's polyethylene core exhibited a wear pattern that was consistent with a disc implanted for years, not months as here. According to Plaintiff, "[Dr. Kropf] did not have an opinion as to the cause of the accelerated wear and other damage." Opp. at 6. But Dr. Kropf appears to have testified that movement or slippage of Ms. Carson's vertebrae (spondylolisthesis) caused this damage:

Q: And so, when you exposed the polyethylene disk . . . did you observe wear that you believe would have been more consistent with . . . years of use? A: Yes. Q: And at that time did you make any, or formulate any opinion as to why that was the case? A: Well, I can't give you an opinion why the polyethylene core broke down in that short a time. **I can give you my opinion that the prosthesis, the disk replacement, was hypermobile, unstable, and created accelerated wear on the core implant.** Q: But even given that, would you have expected the amount of wear that you saw? A: I – I – truthfully, I just thought we were going to see a subluxated implant which appeared to be otherwise intact. I mean, the polyethylene, the end plates would be intact. I wouldn't expect that amount of wear and destruction. (Opp. Ex. J, Dep p. 41.)(emphasis added)

Dr. Kropf, when subsequently questioned by Defendant's attorney, again appears to attribute the advanced

wear and tear to vertebrae slippage:

Q: And the damage that you saw, when you went in and revised Mrs. Carson in November of 2005, that damage was caused by the process [sic] of this unforeseen process of spondylolisthesis leading to impingement, leading to cold flow, leading to the wire snapping, leading to this real badly deformed and broken polyethylene core that you finally had to take out; is that a correct statement? A: Correct. (Motion Ex. E, p. 31).

There is no evidence on which the jury could reasonably find a manufacturing defect, i.e., from accelerated wear. Plaintiff does not provide rebuttal evidence, i.e., that spondylolisthesis did not cause the accelerated wear. Thus, there is no genuine issue of material fact.

B. Breakage

When Dr. Kropf removed the device, it broke into pieces. Plaintiff essentially contends that there is a question of material fact as to whether the device had a manufacturing defect because exposure to oxygen can lead to embrittlement of the polyethylene core. She points out that since the manufacturing process was changed to minimize this possibility, Plaintiff's is the only known instance in which a polyethylene core fragmented. See Opp. Ex. A, dep p. 90. Further, the devices are not individually inspected; they are randomly sampled by lot (and lack individual identification).

However, Dr. Kropf testified that *he* broke the device when he removed it:

Q: At the time, did you have an opinion as to whether it came out in pieces because of, I'll say, your activity, as opposed to it was in different pieces before you began the removal process? A: I don't think it was in different pieces before I removed it.

I think my actions of removing it broke it into pieces, and I can't tell you if -- I can't tell you if the inner core was impaired, and that's why it broke.

But it was my activity that broke it. I pulled it out, and it broke in pieces. (Motion Ex. D, p.22)(emphasis added).

Again, there is no evidence on which the jury could find a manufacturing defect, i.e., from the breakage of the device. Plaintiff does not offer any rebuttal evidence, e.g., that the disk should not have broken even upon removal. Thus, there is no genuine issue of material fact.

C. Other evidence

Dr. Kropf testified it was his practice to visually inspect the device before implanting it, that the core of this device looked normal when he implanted it, and he did not recall observing any abnormality in the device. Motion Ex E, p. 30-31; Motion Ex. B., p. 14-15.

Defendant also submits the affidavit of Robin DiNardo, DePuy Spine's Director of Quality Engineering, who declares that she examined the records of the three lots from which Ms. Carson's components were taken, and basically confirms that the components were manufactured in accordance with specification. The Court finds that the evidence presented in the DiNardo affidavit is inadmissible, pursuant to Plaintiff's objection, based on the Best Evidence Rule. F.R.E.

1002. However, this evidentiary ruling does not alter the Court's ruling and analysis, which does not consider the DiNardo affidavit.

V. Promotion of 'Off-Label' Use

The Charite Disc is indicated for one-level (i.e., for the removal and replacement of *one* spinal disk)—Dr. Kropf's implantation of two disks was therefore 'off-label.' Plaintiff alleges that Defendant negligently promoted this off-label use which was a cause of her injuries. Opp. at 8. To establish a potential for liability, Plaintiff needs to prove (1) that the manufacturer promoted the off-label use in violation of FDA requirements, and (2) that the doctor relied on that promotion in using the device in the off-label manner. *Huntman v. Danek Medical, Inc.*, 1998 U.S. Dist. LEXIS 13431, *25-26 (S.D. Cal. July 24, 1998).

As evidence of promotion, Plaintiff points to DePuy Spine Sales Representative Pre-training

Materials, which contains a slide showing that "Other Indications" include "Multilevel." (Opp. Ex. C.). Plaintiff also alleges that Defendant promotes this off-label use by having its sales representatives attend the actual surgery. Plaintiff cites a training presentation slide which states, "Artificial Disc Surgery is a team sport!" and includes the sales rep along with the physicians, nurse, and tech. (Opp. Ex. I). However, a DePuy officer (William Christianson) testified that the sales rep is present "to make sure that the implants and the instruments are there" and "because frequently the scrub tech needs to know what instrument the doctor wants next." Opp. Ex. A, dep p. 82. Mr. Christianson also testified that they "train the reps not to promote the off-label use," which is "a medical decision . . . . not a sales rep function." *Id.* at p. 85.

Moreover, Plaintiff lacks evidence of Dr. Kropf's reliance on any promotion of off-label usage. There is no evidence that Dr. Kropf was exposed to the above-mentioned slide which noted that "Other Indications" include "Multilevel." Dr. Kropf testified that he decided to implant the disks at two levels based on his own medical judgment, research, and experience. Reply Ex. R, 135-137. The Sales Rep who attended the surgery, Michael "Woody" Hauck, testified that he had no specific recollection of Plaintiff's operation (Opp. Ex. H, depo. p. 13-14), and that he did not recall having any conversations about the surgery with Dr. Kropf. (Motion, Ex. J. 61-62). Dr. Kropf testified that prior to Ms. Carson's implantation, he had no contact with any DePuy sales reps involving discussion of multi-level implantation. Motion Ex. L, p. 73. See also Motion Ex. K, p. 66.

Finally, Plaintiff makes no showing that any promotion caused her injuries. Plaintiff asserts that "[Dr. Kropf] found that if the disc was used in an off-label application, at two levels, the lowest level will have a tendency to fail." (Citing Opp. Ex. J., dep p. 7-8). This assertion is not sufficient to raise a triable issue as to causation. Additionally, the Court notes that Dr. Kropf could not recall whether he had done a multi-level implantation in any patient other than Plaintiff. *Id.*