NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FILED

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U.S. COURT OF APPEALS

CAMILLE CARSON, Plaintiff - Appellant, v. DEPUY SPINE, INC., a corporation, Defendant - Appellee.	No. 08-56698 D.C. No. 2:06-cv-07430-VBF-PLA MEMORANDUM*

Appeal from the United States District Court
for the Central District of California
Valerie Baker Fairbank, District Judge, Presiding

Submitted February 11, 2010**
Pasadena, California

Before: THOMAS and SILVERMAN, Circuit Judges, and BEISTLINE,*** Chief District Judge.

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* This disposition is not appropriate for publication and is not precedent except as provided by 9th Cir. R. 36-3.

** This panel unanimously finds this case suitable for decision without oral argument. See Fed. R. App. P. 34(a)(2).

*** The Honorable Ralph R. Beistline, United States District Judge for the District of Alaska, sitting by designation.

Camille Carson appeals the district court's grant of summary judgment in favor of DePuy Spine, Inc. We affirm. Because the parties are familiar with the facts and procedural history of this case, we need not recount it here.

I

The district court properly granted summary judgment on Carson's negligent manufacturing claim concerning a Charite Artificial Disc, which is manufactured and distributed by DePuy. The disc is a Class III[1] medical device regulated by the Food and Drug Administration ("FDA") under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 360c *et seq.* In October 2004, the FDA granted pre-market approval ("PMA") to DePuy Spine for sale and distribution of the Charite Disc in the United States.

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[1]In 1976 Congress passed the Medical Device Amendments to the FDCA. The amendments established a regulatory regime with various levels of oversight for medical devices, depending on the risks they present. Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls," such as labeling requirements. 21 U.S.C. § 360c(a)(1)(A). Class II, which includes such devices as powered wheelchairs, is subject to "special controls," such as performance standards and postmarket surveillance measures. 21 U.S.C. § 360c(a)(1)(B). Class III, which includes replacement heart valves and pacemaker pulse generators, receives the most federal oversight. The amendments established a rigorous regime of pre-market approval for new Class III devices, and the FDA spends an average of 1200 hours reviewing each application. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The agency approves the labeling of the product, and is free to impose device-specific restrictions by regulation. 21 U.S.C. § 360j(e)(1).

To prove a negligent manufacturing claim under California law, a plaintiff must first show that the product as delivered departed from the governing specifications. A manufacturing defect occurs when the product "differs from the manufacturer's intended result or from other ostensibly identical units from the same product line." *Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 429 (1978). If a product meets the design specifications applicable at the time of manufacture, there is no manufacturing defect. *In re Coordinated Latex Glove Litigation*, 99 Cal. App. 4th 594, 612-13 (2002).

In addition, because the product received pre-market approval from the FDA, Carson must prove the variation in her particular disk was from specifications approved by the FDA. 21 U.S.C. § 360K; *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). Finally, as with any tort claim, the plaintiff must prove the alleged defect caused her injury. *Soule v. GM Corp.*, 8 Cal. 4th 548, 560 (1994).

The district court properly concluded that Carson did not present sufficient evidence creating a genuine issue of fact as to any of the elements of a manufacturing defect claim. The uncontroverted testimony of Dr. Kropf reveals that the disk did not have any visible problems upon implementation, that Carson developed a spinal condition where her vertebrae began moving in a fashion that put extreme stress on the disk, and likely caused the polyethylene to deform in

response to the stressors, and that he himself broke the disk while removing it during the revision surgery in order to complete a spinal fusion that addressed Carson's spinal condition. Carson disputes Kropf's credibility; however, a "party opposing summary judgment may not simply question the credibility of the movant to foreclose summary judgment." *Far Out Productions, Inc. v. Oskar*, 247 F.3d 986, 997 (9th Cir. 2001). Carson did not cite any specific FDA pre-marketing standard or specification that had been violated by any such purported defect.

We see no abuse of discretion in the district court's denial of Carson's request in briefing that it reconsider its manufacturing defect ruling, citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The district court declined to entertain the request because it was untimely and not properly presented. The district court did not abuse its discretion in rejecting the informal reconsideration request on procedural grounds.

In sum, DuPuy's expert testimony was not controverted; no contrary evidence was tendered; and Carson did not identify any federal standard that DuPuy violated in the manufacture of the product. The district court did not abuse its discretion in declining to revisit its ruling. Therefore, we affirm the district court's grant of summary judgment in favor DePuy on the manufacturing defect claim.

II

The district court did not err in granting summary judgment on Carson's claim that DePuy was negligent in allegedly promoting off-label use for its product.

Drugs and medical devices are approved or cleared by the FDA for marketing with labels describing the uses and the patient conditions which have been reviewed in the approval or clearance process. Any use by a physician which differs from the use described in the label or from the patient conditions described in the label is called "off-label."

The FDCA expressly protects off-label use: "Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. In addition, the Supreme Court has emphasized that off-label use by medical professionals is not merely legitimate but important in the practice of medicine. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

The FDA has adopted regulations that limit a drug or device manufacturer's ability to promote a drug or device for off-label use. Therefore, while doctors may use a drug or device off-label, the marketing and promotion of a Class III device

for an unapproved use violates Section 331 of the FDCA. 21 U.S.C. § 331. However, a manufacturer is not liable merely because it sells a device with knowledge that the prescribing doctor intends an off-label use.

Because the FDCA prohibits private enforcement, 21 U.S.C. § 337, Carson asserts a state law negligence *per se* theory predicated on violation of federal law. In California, negligence *per se* is not a separate cause of action but is the application of an evidentiary presumption provided by Cal. Evid. Code § 669. *Quiroz v. Seventh Avenue Center*, 140 Cal. App. 4th 1256, 1285-86 (Cal. 2006). In California, there are four elements required to establish a viable negligence *per se* theory: (1) the defendant violated a statute or regulation; (2) the violation caused the plaintiff's injury; (3) the injury resulted from the kind of occurrence the statute or regulation was designed to prevent; and (4) the plaintiff was a member of the class of persons the statute or regulation was intended to protect. *Alejo v. City of Alhambra,* 75 Cal.App.4th 1180, 1184-1185 (Cal.App. 1999).

The district court correctly concluded that Carson had failed to present sufficient evidence to create a genuine issue as to two of the elements: violation of federal law and causation. A careful review of the record confirms the district court's conclusion. There is no evidence in the record to support Carson's claim that DePuy illegally promoted an off-label use of the Charite Disc, that Dr. Kropf

was influenced by such promotion, or that the off-label use of the disk caused Carson's injury. In fact, the only evidence in the record is to the contrary. Similarly, the record is devoid of evidence of causation. Therefore, the district court appropriately granted summary judgment.

AFFIRMED.