

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 06-21245-CIV-HOEVELER

PATRICK WHEELER,

Plaintiff,

v.

DePUY SPINE, INC.,
a Massachusetts Corporation,

Defendant.

_____ /

**CLOSED
CIVIL
CASE**

**ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT AS TO
CLAIM FOR BREACH OF EXPRESS WARRANTY**

THIS CAUSE comes before the Court on the Defendant's Motion for Summary Judgment as to Plaintiff's claim that Defendant breached an express warranty. The Court heard argument from the parties and listened to testimony from Plaintiff on August 18, 2010, and has determined that summary judgment is appropriate as to this claim.

The Court summarized the pertinent factual and procedural background in a prior Order, and discusses herein only those matters pertinent to the claim for breach of express warranty.

Plaintiff's claim for breach of express warranty alleges that Defendant breached its express warranty to Plaintiff regarding the Charite Artificial Disc because:

- a. The safety of the device was not proven and, rather, the device was unsafe;
- b. The efficacy of the device was not proven and, rather, the device was not efficacious;
- c. The durability of the device was not proven and, rather, the device was not sufficiently durable; and

d. The device does not restore natural motion to the Plaintiff.

Am. Complaint, ¶ 36. Plaintiff bases his claim on a brochure he read, and on his review of the Defendant's website-based information about the Disc, before deciding to proceed with the surgery. Plaintiff's Affidavit, ¶¶ 16-19. At a hearing before this Court, Plaintiff testified that the images on the face of the brochure, submitted as Plaintiff's Exhibit 1, were attractive and showed people participating in activities that Plaintiff was not able to do at the time he read the brochure due to his existing back pain. Plaintiff explained that he focused his attention on the photos of the active people and the statement "natural motion is back" which appears on the cover of the brochure and on the website. A review of the brochure reveals the following statements:

- * Natural motion is back. (Cover of brochure)

- * Laboratory testing shows that the Charite Artificial Disc design allows your spine to move. In the clinical study, patients were observed to have motion between 0 and 21 degrees in flexion/extension (bending forwards and backwards). (Page 2)

- * Complications [of disc replacement surgery] can occur singly or in combination and may include: ... pain or discomfort, paralysis, ... spinal cord or nerve damage, ... the need for additional surgery (Page 5)

The pertinent pages from the website at the time Plaintiff reviewed the site are reproduced as exhibits to the Declaration of Heather Mickool, Defendant's Exhibit 1, and include the following statements:

- * Natural motion is back.TM An alternative to lumbar spinal fusion surgery.

- * Laboratory testing shows that the Charite Artificial Disc design allows your spine to move. In the clinical study, patients were observed to have motion between 0 and 21 degrees while bending forward and backward.

- * Complications [of disc replacement surgery] can occur singly or in combination and may include: ... pain or discomfort, paralysis, ... spinal cord or nerve

damage, ... the need for additional surgery

* The clinical study also demonstrated that patients who received the Charite Artificial Disc had pain relief and restored function no worse than patients who had fusion surgery two years after the surgery. The rates of complications were about the same between the two groups.

* Nobody can guarantee that after disc replacement surgery you will never feel pain again or that your spine will fully regain its flexibility.

Defendant argues that Plaintiff’s claim is pre-empted, and that even if the claim is not pre-empted, Plaintiff cannot meet the requirements of Florida law nor can Plaintiff establish that he was in privity with the Defendant, because a “learned intermediary” performed the disc replacement surgery.

The Court first addresses the question of pre-emption. As noted in this Court’s prior Order, Congress requires that certain medical devices be subject to an extensive review process by the United States Food and Drug Administration (FDA). It is undisputed that the Charite Disc, and the statement “natural motion is back” (found on the website and on the cover of the brochure used to market the Disc), received the FDA’s premarket approval in October 2004. The premarket approval process is governed by the Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c et seq., to the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq.¹ As

¹The MDA includes an express pre-emption clause: Except as provided in subsection (b) of this section, no 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 chapter 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 chapter.

previously noted, if the Court were to allow a claim to proceed for breach of express warranty under Florida law as to the statement “natural motion is back”: “it appears that such a claim would represent a requirement on the manufacturer/device that was “different from or in addition to” the federal requirements – the type of claim pre-empted by the MDA.

The opinion of the Supreme Court in Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), did not specifically address the pre-emption issue with regard to a claim for breach of express warranty. The trial court in Riegel had found that the MDA did not pre-empt a claim for breach of express warranty, although the court ultimately granted summary judgment to the manufacturer on that claim. Id. The trial court determined that “clear, conspicuous and specific language” disclaimed any express warranty. Riegel v. Medtronic, 2003 U.S. Dist. LEXIS 27454 (N.D. N.Y. 2003). The appellate court affirmed the grant of summary judgment without needing to address the issue of preemption, and therefore the issue of whether or not the MDA preempts a breach of warranty claim with respect to a Class III device was not presented to the Supreme Court.

After hearing additional argument from the parties, and reviewing this matter again in detail, I find that Plaintiff’s claim for breach of express warranty must fail. Assuming, without deciding, that this claim is not pre-empted, Plaintiff has not demonstrated a sufficient basis under Florida law for a breach of express warranty. Even if Defendant had been in direct communication with Plaintiff, instead of just

21 U.S.C. § 360k(a).

through a publicly available website and widely available brochure, the statements (and photographic images) upon which Plaintiff claims to rely simply are not an "affirmation of fact or promise" which became "part of the basis of the bargain," Fla. Stat. § 672.313. Moreover, several statements were included in the brochure and on the website which listed the risks involved and the potential for a surgical result of 0 degrees in movement, which stand in clear contradiction to any implied message that a patient would have full range of movement in their back after this disc replacement surgery. Indeed, at the hearing, it appeared that Plaintiff recognized that the statements in the brochure were in some contrast to the image on the cover of the brochure. Plaintiff testified that the cover of the brochure told him everything that he needed to know, implying that he placed greater weight on the message communicated by the cover images than on the clear statement of risk contained in the brochure itself.²

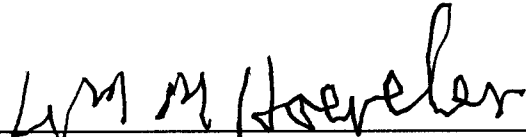
In summary, Defendant has demonstrated that it is entitled to judgment as a matter of law. Even if this Court were to find that the claim for breach of express warranty is not pre-empted, the Court finds that the statements upon which Plaintiff claims to have relied do not constitute an "affirmation of fact or promise" under Florida law. Based on the above, it is

ORDERED AND ADJUDGED that the Defendant's Motion for Summary Judgment be GRANTED as to the claim for breach of express warranty. As the Court

²At the hearing, Defendant offered a copy of the General Consent Form signed by Plaintiff, see Defendant's Exhibit 2. The form includes the following statement: "I have been fully informed of and understand the attendant risks and the possibility of complications, and the medically acceptable alternative to the [disc replacement surgery]" Plaintiff admitted at the hearing that he signed the general consent form, but claimed to have been forced to do so just prior to surgery.

previously granted summary judgment as to Plaintiff's products liability (breach of warranty) and negligence claims, this case is CLOSED.

DONE AND ORDERED in chambers in Miami-Dade County, Florida, this 9th day of September, 2010.



WILLIAM M. HOEVELER
SENIOR UNITED STATES DISTRICT JUDGE

Copies to: Howard Bushman
Peter Flowers
Jeffrey B. Shapiro