IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

KYLE M. SWISHER.	)	
	)	
Plaintiff,	)	
vs.	)	NO. CIV-14-0028-HE
	)	
STRYKER CORPORATION,	)	
CORIN GROUP PLC, and	)	
CORIN USA LIMITED,	)	
	)	
Defendants.	)	

ORDER

Plaintiff Kyle M. Swisher sued defendants Stryker Corporation, Corin Group PLC and Corin USA Limited, asserting negligence per se claims based on defendants' alleged violations of various federal regulations and specifications governing the manufacturing of the Cormet Advanced Hip Resurfacing System (the "Cormet System").[1] Plaintiff dismissed Stryker Corporation and the case proceeded against Corin Group PLC and Corin USA Limited (collectively "Corin" or "defendants"). Defendants have moved for summary judgment, which is appropriate only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). "A genuine dispute as to a material fact 'exists when the evidence, construed in the light most favorable to the non-moving party, is such that a reasonable jury could return a verdict for the non-moving party.'" Carter v. Pathfinder Energy Servs., Inc., 662 F.3d 1134, 1141 (10th Cir. 2011) (quoting Zwygart v. Bd. of Cnty. Comm'rs, 483 F.3d

[1]*See Howard v. Zimmer, Inc., 718 F.3d 1209 (10th Cir. 2013) (Oklahoma law allows parallel negligence per se claims based on violations of federal regulations).*

1086, 1090 (10th Cir.2007)). Having considered the submissions of the parties in light of this standard, the court concludes defendants' motion should be granted.

Plaintiff was implanted on December 28, 2009, with the Cormet hip resurfacing device manufactured by Corin. In his first amended complaint plaintiff alleged two negligence per se claims – that the medical device had manufacturing defects and that defendants used an ineffective quality control testing procedure to test the device. Plaintiff's second claim was based on defendants' asserted use of an inadequate hip simulator test.

After defendants filed their motion for summary judgment, plaintiff moved to amend his complaint and dismiss the second claim with prejudice, without an award of fees or costs to defendants. Plaintiff states in his motion that "discovery simply has not produced evidence sufficient to support Count II, and without access to the information Defendants submitted to the FDA as to their quality control processes, Mr. Swisher has elected to abandon Count II . . . ." Doc. #120, p. 3.[2] He contends he was partially hampered in his ability to obtain evidence to support his claim because specific, detailed information about defendants' qualify control processes is private as a matter of federal law, the discovery he obtained from defendants did not address hip simulator tests or provide useful information on that topic, and "Defendants claimed no hip simulator tests were used in any part of their quality control processes." *Id.* at p. 2. Defendants object to dismissal, asserting plaintiff "should not be permitted to avoid a decision on the merits solely in an effort to cut off

[2]*Page references for briefs and exhibits are to the CM/ECF document and page number.*

Corin's rights to seek costs and fees at the conclusion of the litigation." Doc. #128, p. 2.

Plaintiff was provided with sufficient information from defendants to determine, before they moved for summary judgment, whether or not he could substantiate his quality control claim. Defendants state, and plaintiff does not refute, that he had within his possession for over a year documents produced by Corin, including inspection sheets, *see* Doc. Nos. 111-13, 111-14, which showed that defendants do not use a "hip simulator" quality control test. Corin's 30(b)(6) witness also testified to that effect approximately a month and a half prior to the dispositive motion deadline. Under these circumstances, the court concludes that summary judgment, rather than dismissal, is the appropriate way to dispose of plaintiff's second claim.

As for plaintiff's product defect claim,[3] the court's separate ruling on defendants' Daubert motion[4] effectively resolves that claim. The parties agreed that the materials used in the implant were required by the FDA to comply with the industry standard as provided in American Society for Testing and Minerals ("ASTM") F-75 and that the Cormet was a heat-treated device.[5] Plaintiff's claim was that the device which was implanted in his body did not comply with ASTM F-75. Plaintiff depended on the opinion of Charles W. Powell

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[3]*Although multiple defects were alleged in the first amended complaint, by the time defendants moved for summary judgment plaintiff was relying on only a single claimed defect.*

[4]*Defendants' motion to exclude the opinions of plaintiff's expert Charles W. Powell [Doc. #113].*

[5]*ASTM F-75 sets certain of the specifications and standards for devices like those of the Cormet system.*

to establish the defect and, as his counsel candidly admitted at the Daubert hearing, plaintiff cannot establish his claim without Mr. Powell's testimony.

Mr. Powell essentially opined that because the Cormet device was heat treated its microstructures (specifically the nature of the carbide characteristics) differed from those of non-heat treated devices, resulting in accelerated wear to the components of the device and the increased release of cobalt and chromium into plaintiff's body. The court's Daubert order concluded that Mr. Powell can testify that the Cormet implanted in plaintiff reflected use of a heat treatment in its manufacture and that the heat treatment effected a change in the microstructures of the components. However, he will be prohibited from expressing an opinion that plaintiff's device was defective because it did not comply with ASTM F-75, as the court concluded Mr. Powell lacks the qualifications to offer that opinion and there is no reliable basis for it.

To establish an actionable claim in these circumstances, plaintiff must establish that the device was "defective" in the sense that it did not comply with FDA regulations, i.e. the standards and requirements established by the FDA for the approval of the device. State law claims on any other basis are pre-empted by federal law. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008). Without expert testimony to establish the existence of a manufacturing defect, plaintiff cannot prove his negligence per se claim. *See generally* Howard v. Zimmer, Inc., 299 P.3d 463 (Okla. 2013). Defendants are therefore entitled to summary judgment.

Even if Mr. Powell had been permitted to testify without restriction, defendants would still be entitled to summary judgment because there are other gaps in plaintiff's proof.

Plaintiff offers no expert testimony that his medical device showed abnormal wear.[6] Instead, he relies on the cobalt and chromium levels in his blood based on a blood test conducted on Sept. 2, 2013. He argues that the 6.6 parts per billion ("ppb") level of cobalt and 4.3 ppb level of chromium were two and three times greater than the levels the Federal Drug Administration ("FDA") approved or "anticipated in approving the Cormet System." *See* Doc. #119, pp. 9-10,¶¶ 16, 17 (relying on Exhibit 6, Doc. #119-6, p. 3); p. 26. Plaintiff asserts that "[a]s part of the PMA process, Defendants represented to the FDA that component wear could be anticipated to result in blood metal ion levels of 2.498 for cobalt and 2.405 for chromium." Doc. #119, p. 25 (citing Exhibit 6, Doc. #119-6, p. 3). However, as defendants explain, the study results plaintiff cites were included in a presentation Corin made to the FDA in 2012, five years after the device was approved. *See* Doc. #119-5, p. 2 (July 3, 2007, date of notice of approval of Cormet Hip Resurfacing System). There is no evidence the FDA conditioned the Cormet's approval on a certain permissible metal ion level in patients implanted with the device.

Nonetheless, assuming that evidence of excessive levels of metal ions in plaintiff's blood alone is sufficient to establish abnormal wear in his Cormet device, there is a problem

[6]*Defendants presented expert testimony that, based on various test measurements, the amount of wear measured on plaintiff's device was typical for an implant that had been in the body for 4.5 years. See Doc. #111-1, p. 16. Plaintiff's doctor who removed the device, Dr. Ponder, indicated there was "no evidence of any significant microscopic wear" and that it did not appear to have "abnormal wear." Doc. #111-6, p. 59.*

with the blood sample taken on Sept. 2, 2013. Not only was it "grossly hemolyzed,"[7] Doc. #112-1, p. 2, there are questions about the manner in which the blood was drawn.[8] Dr. Stefan Kreuzer, who saw plaintiff six months after the first blood test, concluded that its results are unreliable "between the hemolysis and inappropriate [collection] technique." Doc. #111-5, p. 9. He ordered a second metal ion test, which was not grossly hemolyzed and showed plaintiff's Cobalt level at 2.1 ppb and Chromium at 2.2 ppb.[9]

Assuming the issues regarding plaintiff's September 2 blood test do not render it totally unreliable and only affect the weight to be given the test results, there is another evidentiary hurdle plaintiff fails to overcome – he has not submitted evidence sufficient to create a justiciable question as to whether the arguably elevated levels of metal ions in his

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[7]*As explained by one of defendants' experts, Dr. James Kudrna, the specimen was grossly hemolyzed because "essentially, all the red blood cells were ruptured in the specimen." Doc. #111-5, p. 8. Plaintiff's physician, Dr. Corey Ponder, testified that it typically is advisable to take another blood sample if a specimen is grossly hemolyzed. Doc. #111-6, p. 9.*

[8]*Defendants filed a motion to strike the affidavit of the physician who drew plaintiff's blood sample because she testified during her deposition that she had drawn plaintiff's blood "pretty much the same as we would any other blood specimen." Doc. #124-3, p. 4. When asked if any special precautions or procedures had been taken for the blood test, the doctor stated, "[n]ot out of the ordinary." Id. Later, after defendants' motion for summary judgment was filed, she stated in an affidavit that she "did not remember employing any special procedures or using any specific equipment for taking Mr. Swisher's blood test on September 2, 2013," but "have since recalled that this was not accurate. I did research proper collection protocols for this type of blood test, obtained special nonmetallic equipment for it, and followed proper collection and handling procedures in taking Mr. Swisher's blood sample on September 2, 2013." Doc. #119-9, p. 2. In the circumstances existing here, it is unnecessary to resolve definitively whether the later affidavit is a "sham" such that it should be disregarded. Suffice it to say, the evidence suggests a very serious question in that regard.*

[9]*Plaintiff asserts that the difference in the test results can be explained by a significant decline in his activity level between September 2013 and March 2014.*

blood caused his alleged injuries.

Defendants' expert, Dr. Kudrna, testified that, to a reasonable degree of medical certainty, plaintiff's reported metal ion levels could not have caused metal toxicity or the neurological symptoms he claimed. *See* Doc. #111-5, pp. 7, 18. Plaintiff responds that Dr. Kudrna "testified that he could *not* state that it was medically impossible for Mr. Swisher's metal ion levels to have caused neurological symptoms." Doc. #119, p. 12. However, reasonable degree of medical certainty, not impossibility, is the standard. *See* Warren v. Tastove, 240 Fed. Appx. 771, 773 (10th Cir. 2007) ("Likewise, we require an opining physician to offer an opinion with a reasonable degree of medical certainty."). Plaintiff also contends that Dr. Kudrna admitted that the dissipation of plaintiff's "neurological symptoms after his Cormet System was removed was 'strong evidence that the cause of those symptoms was the elevated levels of cobalt and chromium[.]'" Doc. #119, p. 12 (quoting Doc. #119-8, p. 5). Reading the cited testimony in context, plaintiff has grossly misstated what the witness said. Dr. Kudrna was discussing a study that did not include the Cormet device, he was not referring to plaintiff, and the patient's level of "serum cobalt" in the study was "over 100 parts per billion." *Id*. at pp. 4-5.

Plaintiff offers no expert opinion or testimony to counter Dr. Kudrna's opinion in his response to defendants' summary judgment motion.[10] Instead, he relies on a file note and a

[10]*As is discussed in the court's Daubert order, it is unclear whether plaintiff's expert, Mr. Powell, intends to testify that the asserted increased amounts of metal ions in plaintiff's body caused his medical or neurological problems. Any such opinion will be excluded because Mr. Powell is not qualified to offer an opinion as to the impact of particular minerals or other substances in a person's body.*

"to whom it may concern" letter prepared by the surgeon, Dr. Corey Ponder, who removed the Cormet device. The note and letter were prepared after Dr. Ponder's initial visit with plaintiff on May 6, 2014. In the note Dr. Ponder stated:

> **ASSESSMENT**: A 55 year-old male with past-medical history significant for ankylosing spondylitis with painful right hip resurfacing with a CORIN Cormet implant with possible neurologic symptoms from cobalt and chromium toxicity with painful right hip resurfacing. Clinical sign and symptoms consistent with possible ALVAL
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> **PLAN**: Patient was seen and examined. History, physical exam, and radiographic findings were discussed at length with the patient. At this point, I think for the symptoms Mr. Swisher is exhibiting, the most prudent thing to do at this time would be revision of his hip resurfacing.

Doc. #119-18, p. 3. In the letter Dr. Ponder said:

> [Mr. Swisher] has an obviously painful right hip resurfacing with signs and symptoms consistent with ALVAL. . . . His only option at this point is a full revision of his hip with the hope of preventing further soft-tissue damage, limiting long term dysfunction, and limiting irreversible systemic effects of cobalt and chromium toxicity.

Doc. #119-19.

The problem with this evidence is that Dr. Ponder subsequently testified that his evaluation of plaintiff on May 6, 2014, was based entirely on plaintiff's self-reporting, as shown by the following deposition excerpt.

> Q. And in your assessment section[11] you indicate there were, quote, possible neurological symptoms from cobalt and chromium toxicity with painful right hip resurfacing, end quote.
> A. Yes, sir.
> Q. And as we discussed before, the possible neurological symptoms here were

[11] *See Doc. #119-18, p. 3.*

based on Mr. Swisher's self-reporting. Right?
A. Yes, sir.
Q. And that you didn't independently verify any neurological symptoms?
A. No, sir.
Q. In fact, in your report you have, in his initial description of his initial assessment, you have neurological symptoms in quotes. Is that correct?
A. Yes, sir.
Q. And the neurological functioning that you examined at the time was normal. Is that correct?
A. Yes, sir.
Q. And in your assessment where you say that the possible neurological symptoms were, quote, from cobalt and chromium toxicity, was that also based on Mr. Swisher's self-reporting"
A. Yes.
Q. Was it based on anything else, sir?
A. No, sir.

Doc. #123-8, p. 6. Dr. Ponder also testified that he could not say to a reasonable degree of medical certainty that plaintiff had ALVAL,[12] Doc. #123-8, p. 7, and that what plaintiff had "reported as high levels of chromium cobalt" was not "a factor in [his] consideration of doing the surgery." *Id.* at p. 8. Contrary to plaintiff's assertion in his brief, neither the note nor the letter, especially when considered in conjunction with Dr. Ponder's subsequent testimony, reflects the necessary "medical findings, to a reasonable degree of medical certainty." Doc. #119, p. 30.[13]

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[12]*Dr. Ponder testified that his assessment of clinical signs of ALVAL was based on the possible pseudotumor which plaintiff had reported, see Doc. #112-3, p. 3, plus the reported pain. Doc. #123-8, p. 7. He made a finding during his revision surgery of "an anterior superior cystic structure consistent with a possible periarticular prosthetic osteolytic cyst or possible pseudotumor." Doc. #119-12, p. 3. Plaintiff admitted, though, that Dr. Ponder did not formally diagnose him with a pseudotumor, Doc. #119, p. 13, and did not diagnose him with ALVAL. Doc. #119, p. 13, ¶29.*

[13]A *number of assertions in plaintiff's briefs are, or border on, flat misrepresentations of the record and some as to Dr. Ponder are particularly egregious. For example, plaintiff asserts that*

Plaintiff had to come forth with some evidence from which a reasonable jury could conclude that the elevated metal ions in his blood were linked to his neurological symptoms. His failure to do this, combined with the other gaps in his proof, particularly the lack of admissible evidence of a product defect, mandates the entry of summary judgment in defendants' favor.

Accordingly, defendants' motion for summary judgment [Doc. #111] is **GRANTED**. Summary judgment in defendants' favor will be granted on both plaintiff's claims. Plaintiff's motion to dismiss his second claim with prejudice [Doc. #120] is **DENIED**. As the court finds it unnecessary to determine whether the affidavit of Dr. Ellis should be stricken to resolve defendants' summary judgment motion, defendants' motion to strike that affidavit [Doc. #124] is **DENIED** as being **MOOT**.[14]

IT IS SO ORDERED.

Dated this 3rd day of February, 2016.

JOE HEATON
CHIEF U.S. DISTRICT JUDGE

"while personally treating Mr. Swisher, Dr. Ponder never made the finding or even mentioned the possibility that Mr. Swisher's symptoms could have been caused by prescription pain medications." Doc. #119, p. 13 (emphasis added.) . To the contrary, in his deposition Dr. Ponder explicitly noted the possibility that plaintiff's "self-reported cognitive issues were the result of heavy smoking and drinking and narcotic use." Doc. #111-6, p. 17 (deposition pp. 70-71). If plaintiff or his counsel are attempting to draw some distinction between what Dr. Ponder mentioned while he was "personally treating" plaintiff, versus a deposition sometime later, the distinction is meaningless in this context and tests the outer limits of reasonable advocacy.

[14]*In the separate order addressing the Daubert motion, the court denied the motion insofar as defendants sought to strike the affidavit of Mr. Powell.*