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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

# Corin Hip Implant Defect Suit Nixed For Lack Of Evidence

By **Steven Trader**

*Law360, New York (February 9, 2016, 10:30 PM ET)* -- An Oklahoma federal judge has ended a man's lawsuit accusing medical device maker Corin of skirting federal regulations and defectively designing a metal-on-metal hip implant system that led directly to his injuries, finding that he simply lacked any proof to support his negligence claims.

Granting Corin Group PLC's motion for summary judgment, U.S. District Judge Joe Heaton said Kyle Swisher couldn't prove his claim that the company hadn't met U.S. Food and Drug Administration standards for manufacturing its Cormet Advanced Hip Resurfacing Device, which allegedly directly caused metal toxicity in his blood that led to his development of "neurological symptoms," according to the Feb. 3 order.

"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," Judge Heaton wrote. "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."

Swisher was implanted with the Cormet hip system in December 2009, but, after allegedly experiencing pain and difficulties with the system, had it removed, and eventually sued Corin and Stryker Corp. in Oklahoma state court, though the case was eventually moved to federal court in January 2014 and Stryker was eventually dropped from it.

In his first amended complaint, Swisher leveled two negligence per se claims against Corin — first that the device was defective and violated federal regulations by elevating metal ion levels in his blood beyond what the FDA had tested the device for, and second that Corin used an ineffective hip simulator test to control its quality.

Though design defect claims on medical devices approved by the FDA under a premarket approval — such as Corin's device — are preempted by the medical device amendment to the federal Food, Drug and Cosmetics Act, Judge Heaton allowed Swisher to proceed into discovery on his negligence claims, on the grounds that he had alleged violations of parallel negligence state law claims, according to court documents.

"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," Judge Heaton wrote in his order. "State law

claims on any other basis are preempted by federal law."

But discovery wasn't kind to Swisher, as he admitted he could not produce the evidence necessary to support his ineffective testing claim and eventually tried to drop it after Corin moved for summary judgment, though Judge Heaton kept it alive for potential litigation costs he might owe.

As for the product defect claim, Swisher's only argument rested on the testimony of one expert, who had opined that the Cormet hip system did not comply with the the American Society for Testing and Material standards approved by the FDA for use in manufacturing the Cormet, which resulted in accelerated wear that raised the cobalt and chromium levels in Swisher's blood. But that was an opinion Swisher's expert lacked the qualifications to make, the judge held.

Even with his expert's testimony though, Swisher wouldn't have been able to prove a defect, Judge Heaton wrote. He offered no evidence that his medical device showed abnormal wear, and instead based his entire claim on one blood test showing elevated metal ions in his blood, the accuracy of which was questioned even by his own doctor, the judge said.

What's more, Swisher had not submitted evidence showing whether the elevated metal ions in his blood even caused the alleged neurological injuries, the judge said. While Corin's expert testified that Swisher's reported metal ion levels couldn't have caused metal toxicity or the neurological symptoms, Swisher never offered a counterargument, Judge Heaton wrote.

The idea that Swisher based his defect claim on the fact that his metal ion blood level was beyond the amount allowed by the FDA wasn't wise, as there is no evidence the FDA conditioned the Cormet device's approval on any certain permissible metal ion level in patients implanted with the device, the judge said.

Andrew Kaplan of Crowell & Moring LLP, who served as lead counsel for Corin, said he was surprised the suit got as far as it did, given that the Cormet device had been approved by the FDA, which normally preempts such cases.

"So I think the significance is that this is the first case, at least for Corin, to really show that the efforts to get around preemption are really just efforts to sidestep the law and are not really genuine claims based on a reasonable factual foundation," Kaplan told Law360. "The win was very important to show that efforts to challenge the design of the device should be rightly rejected under Supreme Court precedent and Congress' intent in their medical device amendment."

Representatives for Swisher did not immediately respond to a request for comment.

Corin is represented by Andrew D. Kaplan, William L. Anderson, Amelia Ashton and Robbie Rogart of Crowell & Moring LLP.

Swisher is represented by Robert G. McCampbell, Mark K. Stonecipher and A. Wayne Billings of Fellers Snider Blankenship Bailey & Tippens PC.

The case Swisher v. Stryker Corp., case number 5:14-cv-00028, in the U.S. District Court for the Western District of Oklahoma.

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